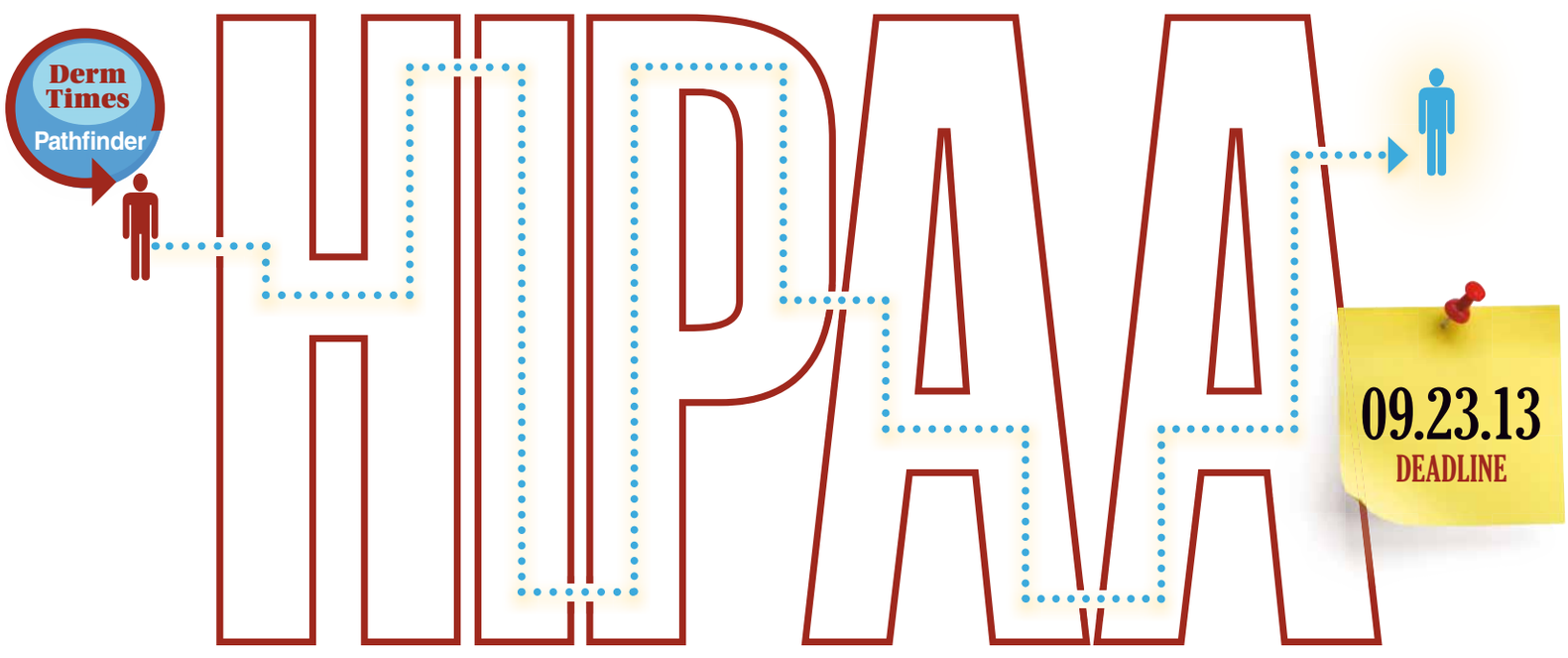
SPECIAL SUPPLEMENT
ACNE
Guidelines improve pediatric acne management
Shape interventions to match patient expectations
Laser, light devices offer more therapeutic options

Dermatology Times®
News and Analysis for Today's Skincare Specialists
DERMATOLOGYTIMES.COM
June 2013 / Vol. 34, No. 6
facebook.com/dermatologytimes
twitter.com/DermTimesNow

Dermatology Times® June 2013 Volume 34 No. 6 Leading News and Analysis for Today's Dermatologists DermatologyTimes.com

New rules increase your liability
Here's how to comply



By Jeff Bendix
Senior Editor

DERMATOLOGISTS HAVE UNTIL SEPT. 23 to put into place internal policies and procedures needed to comply with sweeping changes coming to the Health Insurance Portability and Accountability Act (HIPAA).

24 of 25 say they are not ready

Source: Dermatology Times Facebook poll, May 31, 2013

In January, the Department of Health and Human Services (HHS) released a set of rules, known collectively as the omnibus rule, designed to supplement and modify the privacy, security, breach notification, and enforcement rules governing patient health information in HIPAA.

HHS has made it clear that the Sept. 23 compliance deadline is final. Penalties can range from $100 to $1.5 million depending on the violation.

These changes are a big deal, says Pat Davey, M.D., chairman of the American Academy of Dermatology Practice Management Committee. Every day, someone loses personal information, whether that be a credit card or their Social Security number, he says.

"I've got the feeling that somebody's going to get crucified on the privacy cross ... that'll probably be your solo dermatologist who doesn't have the resources to fight the federal government," he says.

WHAT CONSTITUTES COMPLIANCE?

For dermatologists in private practice, compliance will mean:

→ conducting and documenting a risk analysis, which

HIPAA *See page 64*

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

TOPICORT® (desoximetasone) Topical Spray, 0.25%
Rx Only

BRIEF SUMMARY
1 INDICATIONS AND USAGE
Topicort® Topical Spray is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS
5.1 Effect on Endocrine System
Topicort® Topical Spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

In a study including 21 evaluable subjects 18 years of age or older with moderate to severe plaque psoriasis, adrenal suppression was identified in 1 out of 12 subjects having involvement of 10-15% of body surface area (BSA) and 2 out of 9 subjects having involvement of >15% of BSA after treatment with Topicort® Topical Spray twice a day for 28 days. [*see Clinical Pharmacology (12.2)*]

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency steroids, larger treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.
Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.
Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids. [*see Use in Specific Populations (8.4)*]

5.2 Local Adverse Reactions with Topical Corticosteroids
Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

5.3 Allergic Contact Dermatitis with Topical Corticosteroids
Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

5.4 Concomitant Skin Infections
Concomitant skin infections should be treated with an appropriate antimicrobial agent. If the infection persists, Topicort® Topical Spray should be discontinued until the infection has been adequately treated.

5.5 Flammable Contents
Topicort® Topical Spray is flammable; keep away from heat or flame.

ADVERSE REACTIONS
6.1 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 practice.

In randomized, multicenter, prospective vehicle-controlled clinical trials, subjects with moderate to severe plaque psoriasis of the body applied Topicort® Topical Spray or vehicle spray twice daily for 4 weeks. A total of 149 subjects applied Topicort® Topical Spray.

Adverse reactions that occurred in ≥ 1% of subjects treated with Topicort® Topical Spray were application site dryness (2.7%), application site irritation (2.7%) and application site pruritus (2.0%).

Another less common adverse reaction (<1% but >0.1%) was folliculitis.

Table 1. Number (%) of Subjects with Adverse Reactions Occurring in ≥ 1%

	Topicort® Topical Spray, 0.25% b.i.d. (N = 149)	Vehicle spray b.i.d. (N = 135)
Number of Subjects with Adverse Reactions	13 (8.7%)	18 (13.3%)
Application site dryness	4 (2.7%)	7 (5.2%)
Application site irritation	4 (2.7%)	5 (3.7%)
Application site pruritus	3 (2.0%)	5 (3.7%)

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Teratogenic Effects: Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Topicort® Topical Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels.

Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration at doses 3 to 30 times the human dose of Topicort® Topical Spray based on a body surface area comparison.

8.3 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 breast milk. Because many drugs are excreted in human milk, caution should be exercised when Topicort® Topical Spray is administered to a nursing woman.

If used during lactation, Topicort® Topical Spray should not be applied on the chest to avoid accidental ingestion by the infant.

8.4 Pediatric Use
Safety and effectiveness of Topicort® Topical Spray in patients younger than 18 years of age have not been studied; therefore use in pediatric patients is not recommended. 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 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. [*see Warnings and Precautions (5.1)*]
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 absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. [*see Warnings and Precautions (5.1)*]

8.5 Geriatric Use
Clinical studies of Topicort® Topical Spray did not include sufficient numbers of subjects aged 65 years 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. 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.

10 OVERDOSAGE
Topicort® Topical Spray can be absorbed in sufficient amounts to produce systemic effects. [*see Warnings and Precautions (5.1)*]

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information and Instructions for Use)

Inform patients of the following:
- Use this medication as directed by the physician.
- Topicort® Topical Spray is for external use only. Avoid use on the face, axilla or groin.
- Do not use this medication for any disorder other than that for which it was prescribed.
- Do not bandage or otherwise cover or wrap the treated skin so as to be occlusive.
- Report any signs of local or systemic adverse reactions to the physician.
- Do not use other corticosteroid-containing products with Topicort® Topical Spray without first consulting with the physician.
- Discontinue therapy when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
- This medication is flammable; avoid heat, flame, or smoking when applying this product.
- Discard this product 30 days after dispensed by pharmacist.

Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1
Dist. by: TaroPharma® a division of Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532
Revised: April 2013

AD100-0030

SPECIAL SUPPLEMENT

ACNE

Guidelines improve pediatric acne management

Shape interventions to match patient expectations

Laser, light devices offer more therapeutic options

Dermatology Times®

News and Analysis for Today's Skincare Specialists

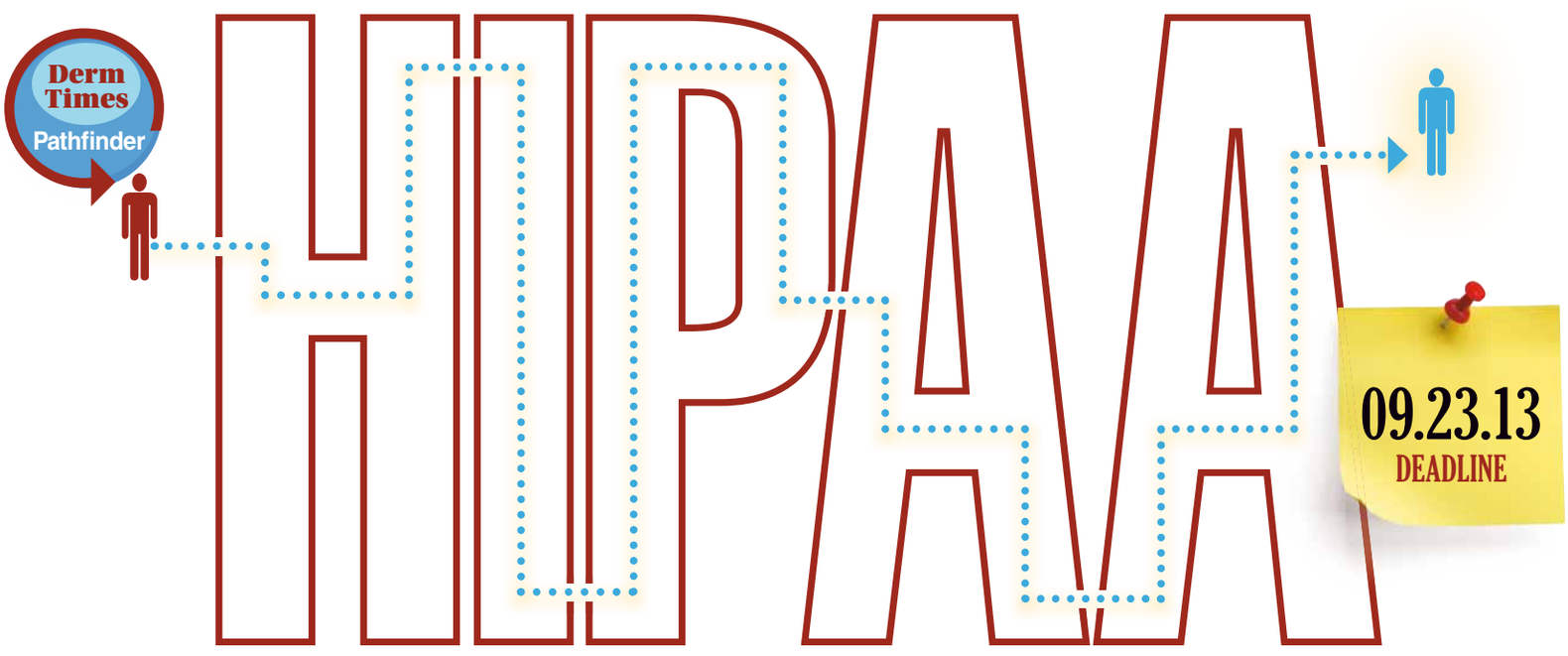
DERMATOLOGYTIMES.COM
June 2013 / Vol. 34, No. 6

facebook.com/dermatologytimes
twitter.com/DermTimesNow

Dermatology Times® June 2013 Volume 34 No. 6 Leading News and Analysis for Today's Dermatologists DermatologyTimes.com

New rules increase your liability

Here's how to comply



By Jeff Bendix
Senior Editor

DERMATOLOGISTS HAVE UNTIL SEPT. 23 to put into place internal policies and procedures needed to comply with sweeping changes coming to the Health Insurance Portability and Accountability Act (HIPAA).

24 of 25 say they are not ready

Source: Dermatology Times Facebook poll, May 31, 2013

In January, the Department of Health and Human Services (HHS) released a set of rules, known collectively as the omnibus rule, designed to supplement and modify the privacy, security, breach notification, and enforcement rules governing patient health information in HIPAA.

HHS has made it clear that the Sept. 23 compliance deadline is final. Penalties can range from $100 to $1.5 million depending on the violation.

These changes are a big deal, says Pat Davey, M.D., chairman of the American Academy of Dermatology Practice Management Committee. Every day, someone loses personal information, whether that be a credit card or their Social Security number, he says.

"I've got the feeling that somebody's going to get crucified on the privacy cross ... that'll probably be your solo dermatologist who doesn't have the resources to fight the federal government," he says.

WHAT CONSTITUTES COMPLIANCE?

For dermatologists in private practice, compliance will mean:

→ conducting and documenting a risk analysis, which

HIPAA *See page 64*

ADVANSTAR
MEDICAL COMMUNICATIONS GROUP

Gentle, Moisturizing Relief

The New Calm for Compromised Skin

Now with the power and efficacy of the Kinetin-Zeatin Complex and exclusive Prosome Delivery Technology

For your patient presenting with erythema, roughness, burning, stinging and dryness associated with rosacea, with the dryness associated with dermatitis and the discomfort she may experience while using her prescribed topical and oral medications.*

When symptoms of burning, stinging and dryness are reduced, your patient may be more compliant with her prescribed therapies.

- Lotion's revised moisturizing formulation is appropriate for all skin types and is non-comedogenic and hypoallergenic
- All Pro+Therapy MD® products are compatible with prescribed treatments and procedures

**Pro+Therapy MD® products are not intended to diagnose or treat disease*

In a clinical trial[1] with Kinetin Lotion 0.1%, Kinetin improved the appearance of the symptoms associated with rosacea in facial skin, with 80% of patients showing an overall improvement at week 12.

[1]Weinstein G, McCullough J, Wu J, et al. Tolerability and Efficacy of a Moisturizing Lotion Containing 0.1% KINETIN for Improving the Signs and Symptoms of Acne Rosacea in Facial Skin. Presented at: American Academy of Dermatology 64th Annual Meeting, San Francisco, CA 2006. The clinical trial was supported by an unrestricted educational grant from Valeant Pharmaceuticals International.

PRO+ THERAPY MD®

MEDICIS®
A DIVISION OF VALEANT PHARMACEUTICALS

Pro+Therapy MD® products are available exclusively through physicians and medical professionals. Learn more about Lotion and the entire family of Pro+Therapy MD® products from your Medicis DTP Aesthetics sales representative or visit www.protherapymd.com/physician

PTMD093-0113

content

CONTENT CHANNEL DIRECTOR **Heather Onorati** } (440) 826-2868 honorati@advanstar.com
CONTENT CHANNEL MANAGER **Sarah Thuerk** } (440) 891-2770 sthuerk@advanstar.com
DIGITAL & INTERACTIVE CONTENT MANAGER **Brandon Glenn** } (440) 891-2638 bglenn@advanstar.com
CONTENT COORDINATOR **Miranda Hester**
CODING COLUMNIST **Inga Ellzey**
COSMETIC COLUMNIST **Zoe Diana Draelos, M.D.**
LASER & LIGHT DEVICES COLUMNIST **Joely Kaufman, M.D.**
LEGAL AFFAIRS COLUMNIST **David J. Goldberg, M.D., J.D.**
GROUP ART DIRECTOR **Robert McGarr** } rmcgarr@advanstar.com
ART DIRECTOR **Lecia Landis** } llandis@advanstar.com
SENIOR PRODUCTION MANAGER **Karen Lenzen** } klenzen@media.advanstar.com

publishing & sales

EVP **Georgiann DeCenzo** } gdecenzo@advanstar.com
VP, GROUP PUBLISHER **Ken Sylvia** } (732) 346-3017 ksylvia@advanstar.com
PUBLISHER **Amy Ammon** } (732) 346-3089 cell: (845) 521-6950 | aammon@advanstar.com
NATIONAL ACCOUNT MANAGER **Diane Kebabjian** } (732) 346-3034 cell: (201) 484-9754 | dkebabjian@advanstar.com
ACCOUNT MANAGER, CLASSIFIED/ DISPLAY ADVERTISING **Karen Gerome** } (440) 891-2670 kgerome@advanstar.com
ACCOUNT MANAGER, RECRUITMENT ADVERTISING **Jacqueline Moran** } (440) 891-2762 jmoran@advanstar.com
BUSINESS DIRECTOR, EMEDIA **Don Berman** } (212) 951-6745 dberman@advanstar.com
DIRECTOR, SALES DATA **Gail Kaye** } (732) 346-3042 | gkaye@advanstar.com
SALES SUPPORT **Hannah Curis** } (732) 346-3055 hcuris@advanstar.com
LIST ACCOUNT EXECUTIVE **Renee Schuster** } (440) 891-2613 rschuster@advanstar.com
PERMISSIONS **Maureen Cannon** } (440) 891-2742 mcannon@advanstar.com

REPRINTS Inquiries involving reprints should be directed to 877-652-5295 ext. 121 bkolb@wrightsmedia.com Outside US, UK, direct dial: 281-419-5725. Ext. 121

audience development

CORPORATE DIRECTOR **Joy Puzzo** } jpuzzo@advanstar.com
DIRECTOR **Christine Shappell** } cshappell@advanstar.com
MANAGER **Joe Martin** } jmartin@advanstar.com

Subscriptions Inquiries, including changes of address, should be directed to (877) 922-2022 or (218) 740-6477.

ADVANSTAR

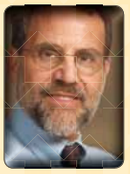
CHIEF EXECUTIVE OFFICER **Joe Loggia**
CHIEF EXECUTIVE OFFICER FASHION GROUP, EXECUTIVE VICE-PRESIDENT **Tom Florio**
EXECUTIVE VICE-PRESIDENT, CHIEF ADMINISTRATIVE OFFICER & CHIEF FINANCIAL OFFICER **Tom Ehardt**
EXECUTIVE VICE-PRESIDENT **Georgiann DeCenzo**
EXECUTIVE VICE-PRESIDENT **Chris DeMoulin**
EXECUTIVE VICE-PRESIDENT **Ron Wall**
EXECUTIVE VICE-PRESIDENT, BUSINESS SYSTEMS **Rebecca Evangelou**
SR VICE-PRESIDENT **Tracy Harris**
VICE-PRESIDENT, MEDIA OPERATIONS **Francis Heid**
VICE-PRESIDENT, LEGAL **Michael Bernstein**
VICE-PRESIDENT, ELECTRONIC INFORMATION TECHNOLOGY **J Vaughn**

Dermatology Times (Print: ISSN 0196-6197, Digital ISSN 2150-6523) is published monthly by Advanstar Communications Inc., 131 W. First St., Duluth, MN 55802-2065. Subscription rates: $95 for one year in the United States and Possessions; $140 for one year in Canada and Mexico; all other countries, $185 for one year. International pricing includes air-expedited service. Single copies (prepaid only): $10 in the United States, $15 in Canada and Mexico, $20 all other countries. Back issues, if available, are $20 in the United States and Possessions, $30 in Canada and Mexico, and $40 in all other countries. Include $6.50 per order plus $2 for additional copy for U.S. postage and handling.If shipping outside the United States, include an additional $10 per order plus $3 per additional copy. Periodicals postage paid at Duluth, MN 55806 and additional mailing offices. POSTMASTER: Please send address changes to DERMATOLOGY TIMES, c/o PO Box 6013, Duluth, MN 55806-6013. Canadian G.S.T. number: R-124213133RT001.Publications Mail Agreement Number 40612608. Return undeliverable Canadian addresses to IMEX Global Solutions, P.O. Box 25542, London, ON, N6C 6B2,Canada. Printed in the U.S.A.

EDITORIAL ADVISORY BOARD

The *Dermatology Times* Editorial Advisory Board qualifies the editorial content of the magazine. Members review meeting programs; suggest story topics, special reports and sources; evaluate manuscripts; conduct interviews and roundtables; and counsel editors as questions arise.

Zoe Diana Draelos, M.D., is consulting professor of dermatology, Duke University School of Medicine, Durham, N.C.



Norman Levine, M.D., is a private practitioner in Tucson, Ariz.

Ronald G. Wheeland, M.D., is a private practitioner in Tucson, Ariz.

Elaine Siegfried, M.D., is professor of pediatrics and dermatology, Saint Louis University Health Sciences Center, St. Louis, Mo.

Dr. Seth Matarasso San Francisco, Calif.

Dr. Ranella Hirsch Boston, Mass.

Dr. David Goldberg New York, N.Y.

Dr. Roy Geronemus New York, N.Y.

Dr. Patti Farris New Orleans, La.

Dr. Tina Alster Washington D.C.

Dr. Albert Yan Philadelphia, Pa.

Dr. Philip Werschler Spokane, Wash.

Dr. Helen Torok Medina, Ohio

Dr. James Spencer St. Petersburg, Fla.

Dr. Joel Schlessinger Omaha, Neb.

Our Mission

Dermatology Times is the only clinical news resource serving a readership of more than 14,000 dermatologists and other professionals focused on skincare. Through unbiased reporting, we strive to help practitioners put into perspective developments that affect their business. Our goal is to provide practical information that will help them to better understand clinical, regulatory and financial issues, as well as chart business growth.

Follow Us!

twitter.com/dermtimesnow

facebook.com/dermatologytimes

sign up for Dermatology Times' weekly newsletter!
dermatologytimes.com/enewssignup

SEE WHAT WE HAVE IN STORE FOR YOU THIS MONTH.

RESOURCES IN DERMATOLOGY

Learn more about devices and products available for hair removal, body shaping, tattoo removal and scar treatment.
dermatologytimes.com/LumenisProducts

Review a broad range of clinical, CME and digital information about psoriatic arthritis. Learn about treatment options to help reduce these symptoms in your patients.
dermatologytimes.com/PsoriaticArthritis

Trending FROM May

Sun exposure may help to reduce blood pressure, demonstrating that the benefits of exposure to UV rays may be greater than the risk of getting skin cancer.
dermatologytimes.com/sunexposure

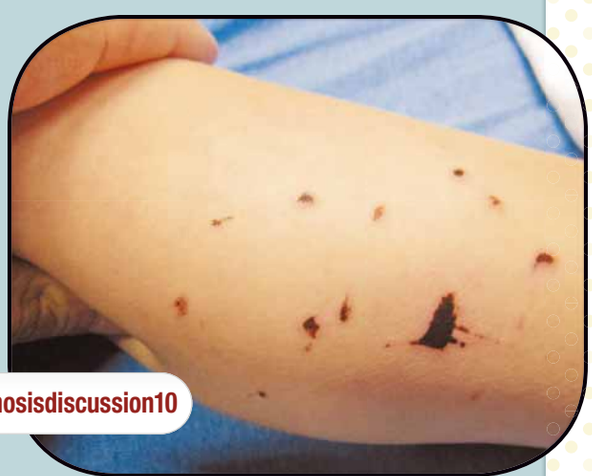
Thyroid disease may have display cutaneous symptoms that dermatologists can identify.
dermatologytimes.com/thyroiddisease

Rhinophyma, a progressive benign condition causing a large, swollen, bulbous nose, can be treated most effectively if identified early.
dermatologytimes.com/rhinophyma

Melasma can be both recurrent and persistent, so it is imperative that clinicians treat it sooner rather than later.
dermatologytimes.com/melasma

What's your diagnosis?

A parent brings his healthy 2-year-old boy to see you. The boy has black spots on his legs that were noted the prior evening. His younger brother developed similar black spots this morning. The boys are healthy, and the lesions are not symptomatic and appear to be superficial. What's your diagnosis?



dermatologytimes.com/diagnosisdiscussion10

Brought to you by *Contemporary Pediatrics* magazine.

The Business of Dermatology

Most patient education materials too hard for patients to understand

A recent study found that the patient education materials of 16 major medical societies were written at too high a reading level, making them hard for patients to understand.

dermatologytimes.com/patiented

How to select appropriate E/M levels, document patient care

You can obtain reimbursement at a higher level and overcome your fears of being audited by thoroughly and correctly documenting the care you provide to your patients.

dermatologytimes.com/medicalcoding

Should you keep your patient's confidence or exonerate?

Chuck Klosterman replies to a physician in the Ethicist column of the New York Times. The physician is facing a bit of a moral dilemma: a patient he had taken care of in the past had disclosed that he had committed a serious crime and allowed another person to take the fall for it.

dermatologytimes.com/confidence

Full face or balding scalp, we've got AKs covered

ZYCLARA® (imiquimod) Cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp in immunocompetent adults.

Avoid use in or on the lips and nostrils. Do not use in or near the eyes.

Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

The safety and efficacy of ZYCLARA Cream has not been established in the treatment of superficial basal cell carcinoma.

See Important Safety Information and brief summary of Full Prescribing Information on the following pages.

Reference: ZYCLARA Cream Package Insert. Scottsdale, AZ: Medicis, the Dermatology Company; February 2012.

MEDICIS®
A DIVISION OF VALEANT PHARMACEUTICALS

FROM HERE

TO HERE

Zyclara®
(imiquimod) Cream
2.5% & 3.75%

BRIEF SUMMARY
(see package insert for
Full Prescribing Information)

ZYCLARA®
(imiquimod) Cream

RX ONLY

FOR TOPICAL USE ONLY
NOT FOR ORAL, OPHTHALMIC, INTRA-ANAL OR INTRAVAGINAL USE

INDICATIONS AND USAGE

Actinic Keratosis

ZYCLARA Cream, 2.5% and 3.75% are indicated for the topical treatment of clinically typical visible or palpable, actinic keratoses (AK), of the full face or balding scalp in immunocompetent adults.

External Genital Warts

ZYCLARA Cream, 3.75% is indicated for the treatment of external genital and perianal warts (EGW)/condyloma acuminata in patients 12 years or older.

Limitations of Use

Imiquimod cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

Treatment with ZYCLARA Cream has not been studied for prevention or transmission of HPV.

Unevaluated Population

The safety and efficacy of ZYCLARA Cream have not been established in the treatment of:

- urethral, intra-vaginal, cervical, rectal or intra-anal human papilloma viral disease.
- actinic keratosis when treated with more than one 2-cycle treatment course in the same area.
- patients with xeroderma pigmentatosum.
- superficial basal cell carcinoma.
- immunosuppressed patients.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Local Skin Reactions

Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. ZYCLARA Cream has the potential to exacerbate inflammatory conditions of the skin, including chronic graft versus host disease.

Severe local inflammatory reactions of the female external genitalia can lead to severe vulvar swelling. Severe vulvar swelling can lead to urinary retention. Dosing should be interrupted or discontinued for severe vulvar swelling.

Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

Systemic Reactions

Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, malaise and chills. An interruption of dosing and an assessment of the patient should be considered.

Lymphadenopathy occurred in 2% of subjects with actinic keratosis treated with ZYCLARA Cream, 3.75% and in 3% of subjects treated with ZYCLARA Cream, 2.5%. This reaction resolved in all subjects by 4 weeks after completion of treatment.

Ultraviolet Light Exposure Risks

Exposure to sunlight (including sunlamps) should be avoided or minimized during use of ZYCLARA Cream. Patients should be warned to use protective clothing (e.g., a hat) when using ZYCLARA Cream. Patients with sunburn should be advised not to use ZYCLARA Cream until fully recovered. Patients who may have considerable sun exposure, e.g. due to their occupation, and those patients with inherent sensitivity to sunlight should exercise caution when using ZYCLARA Cream.

In an animal photo-carcinogenicity study, imiquimod cream shortened the time to skin tumor formation. The enhancement of ultraviolet carcinogenicity is not necessarily dependent on phototoxic mechanisms. Therefore, patients should minimize or avoid natural or artificial sunlight exposure.

Increased Risk of Adverse Reactions with Concomitant Imiquimod Use

Concomitant use of ZYCLARA and any other imiquimod products, in the same treatment area, should be avoided since they contain the same active ingredient (imiquimod) and may increase the risk for and severity of local skin reactions.

The safety of concomitant use of ZYCLARA Cream and any other Imiquimod products has not been established and should be avoided since they contain the same active ingredient (imiquimod) and may increase the risk for and severity of systemic reactions.

Immune Cell Activation in Autoimmune Disease

ZYCLARA Cream should be used with caution in patients with pre-existing autoimmune conditions because imiquimod activates immune cells.

ADVERSE REACTIONS

Clinical Trials Experience: Actinic Keratosis

The data described below reflect exposure to ZYCLARA Cream or vehicle in 479 subjects enrolled in two double-blind, vehicle-controlled trials. Subjects applied up to two packets of ZYCLARA Cream or vehicle daily to the skin of the affected area (either entire face or balding scalp) for two 2-week treatment cycles separated by a 2-week no treatment period.

Local skin reactions were recorded as adverse reactions only if they extended beyond the treatment area, if they required any medical intervention, or they resulted in patient discontinuation from the study. The

Table 1: Selected Adverse Reactions Occurring in ≥ 2% of ZYCLARA-Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Studies (AK)

Adverse Reactions	ZYCLARA Cream, 3.75% (N=160)	ZYCLARA Cream, 2.5% (N=160)	Vehicle (N=159)
Headache	10 (6%)	3 (2%)	5 (3%)
Application site pruritus	7 (4%)	6 (4%)	1 (<1%)
Fatigue	7 (4%)	2 (1%)	0
Nausea	6 (4%)	1 (1%)	2 (1%)
Influenza like illness	1 (<1%)	6 (4%)	0
Application site irritation	5 (3%)	4 (3%)	0
Pyrexia	5 (3%)	0	0
Anorexia	4 (3%)	0	0
Dizziness	4 (3%)	1 (<1%)	0
Herpes simplex	4 (3%)	0	1 (<1%)
Application site pain	5 (3%)	2 (1%)	0
Lymphadenopathy	3 (2%)	4 (3%)	0
Oral herpes	0	4 (3%)	0
Arthralgia	2 (1%)	4 (3%)	0
Cheilitis	0	3 (2%)	0
Diarrhea	3 (2%)	2 (1%)	0

Table 2: Local Skin Reactions in the Treatment Area in ZYCLARA-Treated Subjects as Assessed by the Investigator (AK)

All Grades* (%) Severe	ZYCLARA Cream, 3.75% (N=160)	ZYCLARA Cream, 2.5% (N=160)	Vehicle (N=159)
Erythema Severe erythema	96% 25%	96% 14%	78% 0%
Scabbing/Crusting Severe scabbing/ Crusting	93% 14%	84% 9%	45% 0%
Edema Severe edema	75% 6%	63% 4%	19% 0%
Erosion/Ulceration Severe erosion/ Ulceration	62% 11%	52% 9%	9% 0%
Exudate Severe exudate	51% 6%	39% 1%	4% 0%
Flaking/Scaling/ Dryness Severe flaking/ Scaling/Dryness	91% 8%	88% 4%	77% 1%

* All Grades: mild, moderate or severe

Table 3: Selected Adverse Reactions Occurring in ≥ 2% of ZYCLARA Treated Subjects and at a Greater Frequency than with Vehicle in the Combined Trials (EGW)

Preferred Term	ZYCLARA Cream, 3.75% (N=400)	Vehicle Cream (N=202)
Application site pain	28 (7%)	1 (<1%)
Application site irritation	24 (6%)	2 (1%)
Application site pruritus	11 (3%)	2 (1%)
Vaginitis bacterial*	6 (3%)	2 (2%)
Headache	6 (2%)	1 (<1%)

* percentage based on female population of 6/216 for ZYCLARA Cream 3.75% and 2/106 for vehicle cream

Table 4: Selected Local Skin Reactions in the Treatment Area Assessed by the Investigator (EGW)

All Grades,* (%) Severe, (%)	ZYCLARA Cream, 3.75% (N=400)	Vehicle Cream (N=202)
Erythema* Severe erythema	70% 9%	27% <1%
Edema* Severe edema	41% 2%	8% 0%
Erosion/ ulceration* Severe erosion/ ulceration	36% 11%	4% <1%
Exudate* Severe exudate	34% 2%	2% 0%

* Mild, Moderate, or Severe

incidence and severity of selected local skin reactions are shown in Table 2.

Overall, in the clinical trials, 11% (17/160) of subjects in the ZYCLARA Cream, 3.75% arm, 7% (11/160) of subjects in the ZYCLARA Cream, 2.5% arm, and 0% in the vehicle cream arm required rest periods due to adverse local skin reactions.

Other adverse reactions observed in subjects treated with ZYCLARA Cream include: application site bleeding, application site swelling, chills, dermatitis, herpes zoster, insomnia, lethargy, myalgia, pancytopenia, pruritus, squamous cell carcinoma, and vomiting.

Clinical Trials Experience: External Genital Warts

In two double-blind, placebo-controlled studies 602 subjects applied up to one packet of ZYCLARA Cream or vehicle daily for up to 8 weeks.

The most frequently reported adverse reactions were application site reactions and local skin reactions. Selected adverse reactions are listed in Table 3.

Local skin reactions were recorded as adverse reactions only if they extended beyond the treatment area, if they required any medical intervention, or they resulted in patient discontinuation from the study. The incidence and severity of selected local skin reactions are shown in Table 4.

The frequency and severity of local skin reactions were similar in both genders, with the following exceptions: a) flaking/scaling occurred in 40% of men and in 26% of women and b) scabbing/crusting occurred in 34% of men and in 18% of women.

In the clinical trials, 32% (126/400) of subjects who used ZYCLARA Cream and 2% (4/202) of subjects who used vehicle cream discontinued treatment temporarily (required rest periods) due to adverse local skin reactions, and 1% (3/400) of subjects who used ZYCLARA Cream discontinued treatment permanently due to local skin/application site reactions.

Other adverse reactions reported in subjects treated with ZYCLARA Cream include: rash, back pain, application site rash, application site cellulitis, application site excoriation, application site bleeding, scrotal pain, scrotal erythema, scrotal ulcer, scrotal edema, sinusitis, nausea, pyrexia, and influenza-like symptoms.

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of imiquimod. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Application Site Disorders: tingling at the application site

Body as a Whole: angioedema

Cardiovascular: capillary leak syndrome, cardiac failure, cardiomyopathy, pulmonary edema, arrhythmias (tachycardia, supraventricular tachycardia, atrial fibrillation, palpitations), chest pain, ischemia, myocardial infarction, syncope

Endocrine: thyroiditis

Gastro-Intestinal System Disorders: abdominal pain

Hematological: decreases in red cell, white cell and platelet counts (including idiopathic thrombocytopenic purpura), lymphoma

Hepatic: abnormal liver function

Infections and Infestations: herpes simplex

Musculo-Skeletal System Disorders: arthralgia

Neuropsychiatric: agitation, cerebrovascular accident, convulsions (including febrile convulsions), depression, insomnia, multiple sclerosis aggravation, paresis, suicide

Respiratory: dyspnea

Urinary System Disorders: proteinuria, urinary retention, dysuria

Skin and Appendages: exfoliative dermatitis, erythema multiforme, hyperpigmentation, hypertrophic scar, hypopigmentation

Vascular: Henoch-Schonlein purpura syndrome

OVERDOSAGE

Topical overdosing of ZYCLARA Cream could result in an increased incidence of severe local skin reactions and may increase the risk for systemic reactions.

Hypotension was reported in a clinical trial following multiple oral Imiquimod doses of >200 mg (equivalent to ingestion of the imiquimod content of more than 21 packets or pump actuations of ZYCLARA Cream, 3.75% or more than 32 packets or pump actuations of ZYCLARA Cream, 2.5%). The hypotension resolved following oral or intravenous fluid administration.

Manufactured for:
Medicis, The Dermatology Company
Scottsdale, AZ 85256

April 2012 19110248

Important Safety Information for ZYCLARA (imiquimod) Cream, 2.5% and 3.75%

Intense local skin reactions including skin weeping or erosion can occur after a few applications of ZYCLARA Cream and may require an interruption of dosing. Administration of ZYCLARA Cream is not recommended until the skin is healed from any previous drug or surgical treatment.

Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, malaise and chills.

ZYCLARA Cream should be used with caution in patients with pre-existing autoimmune conditions because imiquimod activates immune cells.

Exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) should be avoided or minimized during use of ZYCLARA Cream. Patients should be advised to wear protective clothing (e.g., hat) when using ZYCLARA Cream.

Avoid concomitant use of ZYCLARA Cream and any other imiquimod cream because of increased risk for adverse events.

In clinical studies, the most common adverse events involved skin reactions in the application area including erythema, scabbing/crusting, flaking/scaling/dryness, edema, erosion/ulceration, and exudate. Most skin reactions were rated as mild to moderate.

insight & opinion from our advisory board leaders

Wm. Philip Werschler, M.D., is an assistant clinical professor at the University of Washington, Seattle.

The cat is out

As the aesthetic industry grows and changes, so can we

With over 2,000 registered attendees and more than 125 vendors, THE Aesthetic Show (TAS) 8th annual presentation in Las Vegas was a resounding success of the integration of traditional, CORE physicians (derms, plastics, facial plastics, ophthalmologists and oral-maxillo facials) and the "new" breed of aesthetic physicians.

These recent arrivals to the field of aesthetic medicine and cosmetic surgery are seemingly everywhere now: academic medical centers, group practices, integrated physician/hospital organizations, solo practitioners, day spas, shopping malls, mobile vans, and yes, even family dental offices.

To try and compare them without distinction is like trying to compare first world and third world healthcare facilities. You can't.

Who are they?

Who are these recent arrivals? It's a tough question to answer.

First, they are you and I: Board certified physicians from U.S. medical schools who have completed one or more residencies, and even fellowships. Some are tenured university professors, others are volunteer faculty. Some are media darlings and television celebrities. Others are prolific authors and clinical researchers. In sum, they are us.

Others are new arrivals led to the stage of aesthetics by evolving healthcare challenges. Some may be seeking refuge from clinical practice frustrations. They could be us.

Still others are seeking a second chance. This road may be an arduous one of visas, FLEX, re-certification and even, at times, of reeducation. They are us — those who haven't had our chances, fortune and success.

They persevere toward a goal of accomplishment at virtually all costs regarding age, family, income and status because they believe in a vision, a goal, a future and, perhaps most importantly, a passion. They are committed. We praise that they want to be like us.

Then there are those motivated by greed, avarice and escape. They are us — those who took a turn away from benevolence; from the adherence to their one-half of the gift of the Hobbesian social contract that so richly rewards the altruistic and humanistic nature of the caring and compassionate and scholarly endeavors of the healers.

In part, they are the redistributionists of the house of medicine. After all, how hard can it be to inject, lase, aspirate or smear on some topical?

Cynical with disparaging attitudes, these naysayers, critics and commentators who must live as pessimists, must only exist on the fringes, don't they? They certainly couldn't be us.

As society pushes forward, for better or worse, with the reorganization of the healthcare system there are certain things that can safely be assumed. Change. For all of its rewards, distractions, benefits and confusion, change will be the main course in the digestion of healthcare reform.

They are us

So who are they? *They* are us — in all of our permutations. *They* are those who choose to pursue passion, to chase a dream at all costs, to re-engineer their lives during the half-time of their careers. Those who are intrigued by the evolving science of beauty and our relentless societal passion to delay, deny and ultimately attempt to defeat father time and Mother Nature. Sadly, there are some, who try and cheat the system. *They* are us, for better or worse.

As an observer, participant and practitioner of the aesthetic arts for a quarter century, I've been standing in the wings while the production of cosmetic medicine has taken place. I've seen, heard and observed the sublime to the ridiculous, the sincere words of richly earned praise to the sarcasm of jealous criticism. I've cringed at the territorial claims of invention of ideas of public domain and common knowledge; I've been there. Yet, as I write this piece, I'm struck by the thoughts of camaraderie — colleagues who are quick to share their thoughts, ideas, visions and desires openly. Yes, aesthetic medicine is us.

Practitioners of the skin are fortunate to have been granted a coveted and original seat at the table of aesthetics. A seat that we share with our equally gracious and adept colleagues, the plastic surgeons. We have much to learn from those who have earned the privilege of completing a second residency (and often one or more fellowships) in plastic and reconstructive surgery. They have saved many dermatologists from the unfortunate outcomes of our interventions, even well-intended. In many ways they are the generals, admirals and field marshals of our time and place. We, as practitioners of the health and beauty of the skin are also fortunate to be welcomed by the other members of the club, the ENT/facial plastic surgeons, the ophthalmic plastic surgeons and the maxilla-facial surgeons. More like allies

EDITORIAL ADVISORY BOARD UPDATE see page 12

Share your thoughts on the evolving aesthetic industry: Tweet @DermTimesNow

SEVERE RECALCITRANT NODULAR ACNE PATIENTS

Introducing a new PARTNER

to help keep them on course

This Toolkit helps you help them defy the odds

New, easy-to-use tools may help your patients meet necessary treatment milestones. Checklists, Q&As, and other tips and resources are included to help more patients succeed.

Call on The Promius Promise to help you navigate the treatment process

Our exclusive pharmacy and support service may help the treatment process flow smoothly for you and your patients with overnight shipping and tracking, frequent reminders, and more. Call us at 1.888.959.7600 to learn more.

David Goldberg, M.D., J.D., is director of Skin Laser & Surgery Specialists of New York and New Jersey; director of laser research, Mount Sinai School of Medicine; and adjunct professor of law, Fordham Law School.

Liability implications

Can a generic drug maker be held liable for injuries?

Dr. Psoriasis, owns a generic manufacturing company that makes a variety of dermatologic medications. He also has a large dermatology practice where he once prescribed a generic medication for his patient who subsequently had a severe life threatening eruption caused by the drug.

Subsequently the patient sued both the dermatologist and his company (the generic manufacturer). The suit was based on allegations that a design flaw in the law led to the serious reaction. Dr. Psoriasis argued that in manufacturing his drug, he simply copied the brand maker's drug — and this is all that is required by federal law.

If the Supreme Court finds that the product defect claims ... are barred by federal law, it would become **virtually impossible** to hold a generic drugmaker accountable for injuries.

That is the question

Can a generic drugmaker be held liable for alleged flaws in the designs of their medication, even though federal law requires generic manufacturer to simply copy the brand drugmaker's design?

This very issue, now being considered by the Supreme Court, is being carefully watched by pharmaceutical companies, regulators and lawyers. It could determine the extent to which individuals can hold generic drug manufacturers liable for injuries allegedly caused by their copycat products.

In this case, Mutual Pharmaceutical Co. has asked the high court to overturn a $21 million jury award to Karen Bartlett, a New Hampshire woman who took Mutual's generic non-steroidal anti-inflammatory drug (NSAID) sulindac in 2004 after her doctor prescribed it for shoulder pain.

Mutual, based in Philadelphia, is a unit of URL Pharma, owned by Sun Pharmaceutical Industries, and manufactures dozens of generic drugs ranging from antibiotic doxycycline to the antifungal nystatin. The trial judge upheld the jury's award, and a federal appeals court agreed, describing Bartlett's experience as "disastrous."

Patient fallout

Doctors diagnosed her with Stevens Johnson Syndrome that developed some three weeks after Bartlett started taking it. Her skin began to peel off, leaving her with burn-like lesions over two-thirds of her body. She spent close to two months in a hospital burn unit, some of that time in a medically induced coma, and has since undergone 13 eye surgeries.

Her severe form of Stevens-Johnson Syndrome left Bartlett with permanent near-blindness, scarred lungs and a constricted esophagus that makes it difficult to swallow. She sued Mutual in 2008 for alleged design defects under New Hampshire law.

After a 14-day trial, a jury awarded Bartlett $21 million for her injuries.

Asking the Supreme Court to overturn the award, Mutual argues that federal law bars such claims because its drug had already been approved by the U.S. Food and Drug Administration and federal law requires generic drugs to have the same design as their brand-name equivalents.

The company cites a 2011 Supreme Court ruling, PLIVA v. Mensing, which dramatically constrained consumers' ability to sue generic manufacturers over alleged injuries. In that case, the court found that generic drugmakers could not be sued for failing to warn about certain health risks because federal law requires brand-name and generic drugs to carry the same label. That ruling has wiped out the bulk of personal injury cases against generic manufacturers.

Bartlett's case, it has been suggested, attempted to skirt the Mensing ruling by claiming that the generic drug was inherently dangerous, based of the number of incident reports, from the generic drug of the skin reaction submitted to the FDA. From that data, Bartlett concluded that sulindac's design was unreasonably dangerous and defective.

Mutual argued that the logic of Mensing should also apply to design defect claims because, as with their labels, generic drug companies have no control over their product's design.

But in May a unanimous three-judge panel of the 1st Circuit Court of Appeals in Boston refused to extend the ruling to design defect claims. The court ruled that Mutual could simply have decided to stop making sulindac, based on the brand name Clinoril, and take it off the shelves.

If the Supreme Court finds that the product defect claims under state law are barred by federal law, it would become virtually impossible to hold a generic drugmaker accountable for injuries caused by their products.

About 80 percent of all U.S. prescriptions are filled with generics, according to healthcare information provider IMS Health. When a doctor prescribes a brand-name drug, state laws allow pharmacists to automatically substitute the cheaper generic version in filling the prescription. In fact, Bartlett's doctor did prescribe the brand-name Clinoril, but her pharmacist filled it with the generic sulindac.

The implication of the Supreme Court ruling and its impact on Dr. Psoriasis becomes clear. DT

accentskinhealth.com

INTRODUCING A NEW WAY TO TAME THE BEAST

PROTEASE TECHNOLOGY

Living with dry, itchy, scaly skin can be a beast. As part of a daily skincare regimen, accént™ Cleansing Wash and accént™ Moisturizing Lotion help manage dry, itchy, flaky skin associated with common skin conditions like atopic dermatitis and psoriasis. The difference is in Protease Technology, a unique blend of plant-based enzymes that you won't find in any other cleansers or moisturizers. Recommend these accént™ products for daily use and help keep the beast under control.

TaroPharma®

AD940-0001 May 2013

Advisory board update from page 8

than competitors I would posit. We, collectively, are us.

Where do we go from here?

Nature abhors a vacuum. When it seems like no one else can sit at the table, they build a new table, for better or worse. At what cost does this construction take place? What would Galen, who is generally credited with introducing the concept of prognosis, have to say about the future of the aesthetic roundtable? I would hope that he would find teaching and inclusivity as a hallmark feature of the members of our fraternity (or sorority, if you please). That we would choose wisely to facilitate those who wish, for all of the right reasons, to study our tradecraft of aesthetic medicine; to open the door to new ideas generated by those who are not yet us, but approach the threshold with altruism and not avarice.

I've evolved in politics (shudder at the comparison) in my viewpoints, as I've watched, listened, and observed. I've climbed up and down and back up again

in the social ladder of pecking order in aesthetic medicine, with an attempt to be open-minded. I've learned that there are others in our house who study the skin, too. I've been humbled, yet impressed by their hard work and commitment. Who am I to criticize their efforts? Why would I defend barring the entry to those with noble intentions? Am I a teacher? I did take the Hippocratic Oath which in part reads:

"…To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own brothers, to teach them this art; and that by my teaching, I will impart a knowledge of this art to my own sons, and to my teacher's sons, and to disciples bound by an indenture and oath according to the medical laws, and no others."

So I have opened my eyes to the fortune I've been granted, to be a dermatologist, a physician and yes, a practitioner of the aesthetic arts. I'm lucky, and I think I've begun to realize it. In doing so, I ask myself "Who am I to deny access to others who wish to do what I do?" And thus I teach to those who want to learn, to those who seek out knowledge and to those who want to do what I do. For all of the right reasons I want them to become one of us. Thank you. DT

Wm. Philip Werschler, M.D.

RESEARCH NEWS

Aging physicians should be required to undergo competency and health screening, study says

San Diego — Beginning at the age of 70, physicians' physical health, mental health, and cognition skills should be evaluated to determine whether they should continue practicing medicine, according to a paper recently published in the *Journal of Medical Regulation*.

It's a controversial recommendation as many doctors believe that the practice of medicine is over-regulated and that physicians are losing their autonomy.

Regardless, what's beyond debate is that the U.S. physician population is aging, according to data from the study, called "Approaching the Issue of the Aging Physician Population." In 1985, the number of active physicians in practice was 476,683, with 9.4 percent aged 65 or more years. In 2011, physicians in active practice numbered 697,340, with 15.1% aged 65 or more years.

"The public thinks that physicians' health and competence is being vigorously monitored and assessed. It isn't," William Norcross, MD, one of the study's authors, told Kaiser Health News last year.

Other professions are subject to age-related regulations. For example, airline pilots must undergo regular health screenings starting at age 40 and must retire at age 65. FBI agents must retire at age 57, Kaiser reports.

But is older age associated with increased risk of patient harm? The authors reviewed 62 published studies. More than half of those studies found declining clinical performance outcomes with increased age. One showed improvements in all outcomes with greater age.

"Aging results in a wide spectrum of physiological changes which may affect clinical competence," the authors write. "Amongst the most important are the reductions in dexterity and visual-spatial acuity, short-term memory, problem-solving, and ability to adopt new ideas and to re-examine old ideas."

Still, the authors point out the positive psychological aspects of aging: Attributes such as optimism, resilience, compassion, and wisdom do not decline but stay stable or even increase with age, they say.

Nonetheless, patients with highly complex conditions, certain major operations, and multitasking confer higher patient risk with older physicians, the authors write.

The researchers state that they do not favor a mandatory retirement age for physicians for a variety of reasons, including that age in and of itself hasn't been linked with incompetence. But they do favor age-based screening.

"The evidence, however, does point to a need for evaluation of mental and physical health at appropriate junctures throughout a physician's lifecycle," they write. "A call for a process beyond self-regulation is warranted."

Although age-based screening may be a thorny issue that many doctors would prefer to avoid confronting, the authors warn that if physicians don't address the issue themselves, it's likely that someone else will.

"Physicians must take the lead in addressing this important issue. …The medical profession should act now, lest others dictate the direction of this important issue," they write. **DT**

QUICKTAKES

FDA, SANDOZ RECALL METHOTREXATE

Washington — The FDA announced that Sandoz is conducting a voluntary recall of its Methotrexate Sodium USP, 25 mg/mL, 40 mL injectable products. The manufacturer discovered particulate matter in vials during a routine quality inspection of retention samples. The two lots recalled are CL0996 (expiration date 12/2013) and CJ4948 (expiration date 05/2013). These lots were distributed nationally across the United States and to Poland, according to the FDA safety alert. Although Sandoz is not aware of any related adverse events, use of injections from the affected lots can lead to microembolisation in areas where the particles lodge, FDA warns. Healthcare professionals are asked to report any adverse reactions or quality problems involving this product directly to the Sandoz Drug Information Direct Line at 800-525-2492. Adverse events should also be reported to the FDA's MedWatch Safety.

NMSC LINKED TO LOWER ALZHEIMER'S RISK

Bronx, N.Y. — Older patients who have nonmelanoma skin cancer (NMSC) may have a significantly lower risk of developing Alzheimer's disease, a recent study published online May 15 in the journal *Neurology* indicates. Researchers from the Saul B. Korey Department of Neurology Albert Einstein College of Medicine, Bronx, N.Y., evaluated 1,102 patient volunteers aged 70 years and older and obtained self-reported cancer information to examine the association between NMSC and subsequent risk for developing Alzheimer's disease. After adjusting for demographics, hypertension, diabetes, and coronary heart disease, prevalent NMSC was only associated with reduced risk of AD (hazard ratio = 0.21; 95 percent confidence interval = 0.051–0.87; p = 0.031), the researchers wrote. The researchers did not find any significant association between NMSC and subsequent AD or all-cause dementia.

ONE-THIRD OF PRACTICES WANT TO REPLACE EHRS

Austin, Texas — More than 31 percent of medical practices say they're replacing their old electronic health records (EHRs) systems with new ones, according to Software Advice, a company that aims to match software buyers with the right systems for them. Dissatisfaction was cited as the most frequent reason behind the switch.

The figure represents a jump of 10 percentage points from a similar survey in 2010. The results are similar to those of a much larger survey earlier this year. Aside from general dissatisfaction, the most-often cited reasons for switching were desire for a fully integrated system, a current EHR that's "old" or "unsupported," cost implications, and concerns about compliance and meaningful use.

The Importance of the Unique MetroGel® (metronidazole) Gel 1% HSA-3® Vehicle on Skin Barrier Function for Patients With Rosacea

COMPROMISED SKIN BARRIER OF ROSACEA PATIENTS

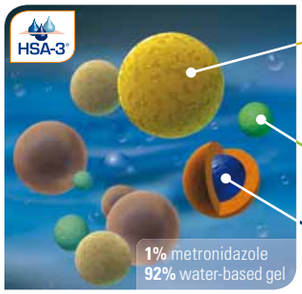
The skin of patients with rosacea is extremely sensitive and sufferers frequently experience physical discomfort, burning sensation, facial itching, stinging, and swelling.[1-4] Research shows that a deficient stratum corneum (SC) may be responsible for many of the signs and symptoms of rosacea. It is essential to select a topical rosacea treatment that enhances SC barrier function as it may help improve skin sensitivity and reactivity, and help reduce sensory rosacea symptoms such as facial burning/stinging.[1,4,5]

THE IMPORTANCE OF THE VEHICLE IN TOPICAL ROSACEA TREATMENT SELECTION

The vehicle of a topical rosacea therapy can be as important as the active ingredient. In fact, **the vehicle may account for 50% to 75% of treatment efficacy**. The vehicle should: **1. Maintain activity of the medication; 2. Repair and/or not further damage the skin barrier; 3. Allow penetration of the active ingredient; 4. Deliver the correct dose; 5. Be easy to use and well tolerated**. A vehicle that carries out all of these activities will help optimize the efficacy and tolerability of the therapy, which may help increase patient comfort and compliance.[1,2]

THE TECHNOLOGICALLY ADVANCED METROGEL 1% HSA-3 VEHICLE PROVIDES MOISTURIZING BENEFITS

MetroGel 1% is the only topical rosacea treatment with a vehicle that contains HSA-3—the hydrosolubilizing agents niacinamide, propylene glycol, and beta cyclodextrin (betadex)—to help protect the skin barrier and facilitate drug delivery.[1]



Niacinamide (vitamin B3) is believed to have broad effects in facilitating normal skin metabolism. Niacinamide has been shown to improve skin barrier function by increasing epidermal lipid and protein production, reducing transepidermal water loss (TEWL) and increasing the skin's resistance to common irritants and barrier-damaging agents. Niacinamide is an essential component of metabolic pathways involved in both cellular survival and cellular death, and has been shown to improve skin texture, blotchiness, and uneven pigmentation.[1,2,6]

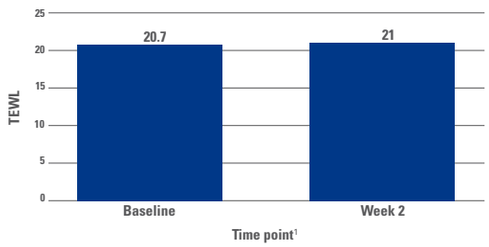
Propylene glycol promotes permeation and penetration of the SC by diffusing into the SC and changing the skin's solubility properties. It has been shown that propylene glycol is important for maximizing metronidazole penetration through the SC.[2,7-9]

Betadex has a polyhydric hydrophilic exterior, resulting in good water solubility and skin moisturization, and helps to reduce irritation after topical drug administration.[1,2]

METROGEL 1% IN UNIQUE HSA-3 VEHICLE HELPS PROTECT BARRIER FUNCTION

A study* evaluating the impact this topical treatment has on skin barrier function demonstrated that MetroGel 1% and its novel HSA-3 vehicle did not damage the skin barrier and may have additional barrier-enhancing effects on skin. This was evidenced by no increase in TEWL and no decrease in corneometry (skin hydration).[1]

The study revealed no damage to the skin barrier following 2 weeks of treatment with MetroGel 1%, as reflected by no worsening of TEWL or corneometry measurements. In fact, there was a trend toward statistically significant improvement in skin corneometry at the end of the 2-week study period (P=.052).[1]



> *Studies have shown the scientifically advanced HSA-3 vehicle of MetroGel 1% does not disrupt the already compromised skin barrier and may enhance barrier function by increasing skin hydration. This may help reduce skin sensitivity, burning, stinging, and other symptoms of rosacea.*
>
> —*Patricia K. Farris, MD*
> *Metairie, Louisiana*

HSA-3: NOT ALL VEHICLES ARE CREATED EQUALLY

The technologically advanced vehicle of MetroGel 1% does more than simply function as an inert drug carrier; this active vehicle has increased hydration and no disruption of the skin barrier, which enhances this topical treatment. Generic forms of the active drug are available but the vehicles are not standardized, which may change the efficacy and tolerability of a product.[1,2]

CONCLUSION

MetroGel 1% is the only topical rosacea therapy in a measured-dose pump with the scientifically advanced HSA-3 vehicle—providing a combination of efficacy, tolerability, and convenience for rosacea patients. There is no generic substitute for MetroGel 1% 55-gram Pump.[1,2,10]

Important Safety Information

Indication: METROGEL® 1% is indicated for the topical treatment of the inflammatory lesions of rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with METROGEL® 1% were nasopharyngitis, upper respiratory tract infection, and headache. Other adverse experiences reported when using topical metronidazole include skin irritation, transient redness, metallic taste, tingling or numbness of the extremities and nausea. **Warnings/Precautions:** METROGEL® 1% should not be used by patients who are allergic to metronidazole or any ingredient in METROGEL® 1%. Avoid contact of METROGEL® 1% with the eyes as it may cause tearing. METROGEL® 1% should be used with caution in patients with evidence of, or a history of, blood dyscrasia, and with patients taking blood thinning agents as they may experience prolonged prothrombin times. METROGEL® 1% treatment should be discontinued if numbness or paresthesia of any extremity should occur.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

*A total of 25 female subjects ranging from 20 to 75 years of age with mild to moderate rosacea were assessed by the investigator to determine the effect of MetroGel 1% in the HSA-3 vehicle on skin barrier function.[1]

Dr Farris is a paid consultant for Galderma Laboratories, L.P.

IMPORTANT INFORMATION ABOUT

METROGEL®

(metronidazole) gel, 1%

BRIEF SUMMARY

This summary contains important information about METROGEL Gel. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking METROGEL Gel. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about METROGEL Gel. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS METROGEL GEL?

METROGEL® (metronidazole) Gel, 1% is a prescription topical medication to treat the bumps and blemishes (inflammatory lesions) on the face caused by a condition called rosacea.

WHO IS METROGEL GEL FOR?

METROGEL Gel is for use in adults. The safety and effectiveness of METROGEL Gel in pediatric patients has not been established.

You **should not** use METROGEL Gel if you are allergic to metronidazole or to any other ingredient of the formulation. If you are not sure, talk to your doctor or pharmacist.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING METROGEL GEL?

Tell your doctor about all your health conditions and medications, especially if you

- are pregnant or planning to become pregnant.
- are breastfeeding.
- have or had a central nervous system disease.
- have a blood disorder.
- are taking blood thinners (anticoagulants).

WHAT SHOULD I AVOID WHILE USING METROGEL GEL?

Topical metronidazole has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF METROGEL GEL?

The most common side effects of METROGEL Gel are

- sore throat / nasal congestion.
- upper respiratory tract infections.
- headaches.

METROGEL GEL may also cause

- skin irritation.
- transient redness.
- metallic taste.
- tingling or numbness of extremities.
- nausea.
- tearing of the eyes.

These are not all of the possible side effects of METROGEL Gel. For more information, ask your doctor or pharmacist.

You are also encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

HOW SHOULD I USE METROGEL GEL?

- Use METROGEL Gel exactly as prescribed by your doctor.
- Unless you have been instructed otherwise, apply and rub in a thin film of METROGEL Gel once daily to affected area(s).
- A gentle cleanser should be used before the application of METROGEL Gel.
- Cosmetics may be applied after the application of METROGEL Gel.
- For external use only. Not for oral, ophthalmic or intravaginal use.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT METROGEL GEL?

- Talk to your doctor or pharmacist
- Go to **www.metrogel.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P.,
Fort Worth, Texas 76177 USA

Revised: February 2013

References: 1. Draelos ZD. Assessment of skin barrier function in rosacea patients with a novel 1% metronidazole gel. *J Drugs Dermatol.* 2005;4(5):557-562. **2.** Jackson JM, Pelle M. Topical rosacea therapy: the importance of vehicles for efficacy, tolerability and compliance. *J Drugs Dermatol.* 2011;10(6):627-633. **3.** National Rosacea Society. New survey documents prevalence of burning, stinging and itching. *Rosacea Review.* http://www.rosacea.org/rr/2006/winter/article_3.php. Accessed April 3, 2013. **4.** Farris PK. Skin care based on science: improving outcomes in rosacea. *Cosmetic Dermatol.* 2012;25(2):72-78. **5.** National Rosacea Society. Treating rosacea and seborrhea. *Rosacea Review.* http://www.rosacea.org/rr/2012/summer/article_4.php. Accessed April 3, 2013. **6.** Bissett D. Topical niacinamide and barrier enhancement. *Cutis.* 2002;71:8-12. **7.** Otto A, du Plessis J, Wiechers JW. Formulation effects of topical emulsions on transdermal and dermal delivery. *Int J Cosmet Sci.* 2009;31:1-19. **8.** Fisher AA. Reactions to popular cosmetic humectants. Part III. Glycerin, propylene glycol, and butylene glycol. *Cutis.* 1980;26:243-244, 269. **9.** Wagner N, Berthaud C, Laffet G, Caron JC. Differential penetration of skin by topical metronidazole formulations. *Adv Ther.* 1998;15:197-205. **10.** Data on file. Galderma Laboratories, L.P.

Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
METR-008 Printed in USA 05/13

www.metrogel.com/hcp

GALDERMA
Committed to the future of dermatology

metrogel 1%®
(metronidazole) Gel, 1%

REGULATORY NEWS

Preliminary data support ArteFill as possible long-term acne scar therapy

San Diego— ArteFill may fill a void in the long-term treatment of acne scarring, interim data indicates.

In an ongoing study being conducted by Suneva Medical, patients whose acne scars were treated with ArteFill had a statistically significant improvement in appearance compared with a control group as early as six weeks after treatment.

Researchers randomly assigned approximately 130 patients to receive treatment with ArteFill or saline. Treatment success was determined by at least half of a patient's scars showing a two-point improvement on an Acne Scar Response Scale. Two-thirds of patients treated with ArteFill demonstrated this improvement compared with one-third of those in the control group.

Physicians and subjects reported statistically significant improvements in appearance in patients treated with ArteFill compared with the control group at six months. On a Subject Assessment of Scar Correction scale, patients treated with ArteFill demonstrated a statistically significant higher degree of satisfaction at six months compared with the control group.

Forty percent of patients enrolled were male. Additionally, 26 percent had Fitzpatrick skin type of V or VI.

Researchers found no statistically significant difference in adverse event rates between groups at six months. Treatment-related adverse events were rare, mild and resolved, the researchers reported.

The safety portion of the study will continue through the end of the year, at which time data will be submitted to the FDA with the goal of gaining approval for the treatment of acne scars, according to Suneva. **DT**

RESEARCH NEWS

Nearly half of eligible providers have received EHR incentive payments

Baltimore — Forty-four percent of the nation's eligible providers have received electronic health records incentive payments from the federal government, according to CMS.

Forty-four percent of the nation's eligible providers have received electronic health records (EHR) incentive payments from the federal government, according to the Centers for Medicare and Medicaid Services (CMS).

That equates to about 230,000 providers who are "meaningfully using" EHR technology, CMS said in a statement.

More than 388,000 providers — about 73 percent of those eligible — have registered for the program, according to CMS. As of the end of March, the federal government had paid about $13.7 billion to providers under the EHR incentive program, which began making payments in 2011.

There's little doubt that most physicians are pleased to receive payments to help them defray the costs of EHRs, but to what extent they're pleased with their EHR systems is another matter.

A survey of 17,000 active EHR users earlier this year found that 23 percent of physician practices are frustrated enough with the software to consider switching vendors.

Separately, another survey this year found that user satisfaction with EHRs is in decline, down 12 percentage points from 2010 to 2012. At the same, time, the percentage of users who classified themselves as "very dissatisfied" with their EHRs increased 10 percentage points.

A recent report by six Senate Republicans took note of rising concerns with EHRs. The report cited five major concerns with the Health Information Technology for Economic and Clinical Health (HITECH) Act, a 2009 law that appropriated $35 billion to promote the use of HIT by physicians, hospitals, and other health providers. Those concerns were lack of interoperability among EHR systems, increased costs, lack of oversight, risk to patient privacy, and a lack of clarity on the program's sustainability. **DT**

Calorie restriction may improve psoriasis

Baltimore — Calorie restriction may improve psoriasis symptoms in overweight patients with osteoporosis, a new research from the Copenhagen University Hospital Gentofte, Denmark, suggests.

According to researchers, it appears that weight loss may reduce obesity-induced inflammation, which subsequently impacts the skin disease.

The randomized clinical trial involved 60 overweight patients with psoriasis at a university hospital outpatient dermatology clinic (ages 25-71 years). Patients were selected at random for one of two groups: intervention group with a low-energy (calorie) diet (LED, 800-1,000 kcal/day) and a control group that maintained their current diet of healthy foods. Researchers assessed the Psoriasis Area and Severity Index (PASI) after 16 weeks and the Dermatology Life Quality Index (DLQI).

By the 16th week, the intervention group's mean body weight loss was approximately 34 pounds more than mean body weight loss in the control group. The mean differences in PASI and DLQI, which additionally supported the intervention group, were -2.0 and -2.0, respectively, according to study results.

"Our results emphasize the importance of weight loss as part of a multimodal treatment approach to effectively treat both the skin condition and its associated comorbid conditions in overweight patients with psoriasis," the authors state.

The findings were published online by *JAMA Dermatology* on May 29, 2013. **DT**

REGULATORY NEWS

FDA approves two melanoma drugs

Washington — The FDA approved two drugs and a companion diagnostic for the treatment of advanced metastatic melanoma, the organization announced.

Tafinlar (dabrafenib) is a BRAF inhibitor approved to treat melanoma tumors that express the BRAF V600E gene mutation. Mekinist (trametinib) is a MEK inhibitor that is approved to treat tumors that express either the BRAF V600E or V600K gene mutations. The drugs are approved as single agents, not as a combination treatment, according to the agency's news release.

The companion genetic test, called THxID, is aimed at helping doctors determine which BRAF genetic mutation, a patient's melanoma cells carry. It's approval is based on evaluation of its use during the trials for both dabrafenib and trametinib, in which it was used to select patients.

Approximately half of melanomas carry a BRAF gene mutation, the FDA says.

Zelboraf (vemurafenib, Genentech) and Yervoy (ipilimumab, Bristol-Myers Squibb) were approved for the treatment of metastatic melanoma in 2011, the agency notes.

The approval for dabrafenib comes after study results indicated that tumor growth was delayed 2.4 months longer in patients taking the drug compared with those receiving the chemotherapy drug dacarbazine. The trial randomly assigned 250 patients with BRAF V600E gene mutation-positive metastatic or unresectable melanoma to receive treatment with dabrafenib or dacarbazine.

Side effects reported by patients included hyperkeratosis, headache, fever, joint pain, non-cancerous skin tumors, hair loss and hand-foot syndrome. Serious, but less common adverse events included an increased risk of cutaneous squamous cell carcinoma, fever due to hypotension, rigors, dehydration, kidney failure and hypoglycemia requiring changes to or the initiation of diabetic treatment.

The study for trametinib randomly assigned 322 patients with metastatic melanoma carrying the BRAF V600E or V600K gene mutations to receive either trametinib or chemotherapy. Results demonstrated that trametinib delayed tumor growth 3.3 months longer than chemotherapy. However, patients previously treated with other inhibitors of BRAF, including dabrafenib, did not show any benefit in this study, the FDA notes.

Common side effects reported were rash, diarrhea, peripheral edema, and acne-like breakouts. Serious side effects included skin infections, pulmonary inflammation, heart failure and vision loss.

Both drugs may carry a potential risk to unborn fetuses in women of childbearing age, as well as potential infertility in both men and women.

GlaxoSmithKline markets dabrafenib and trametinib. The THxID BRAF Kit is marketed by bioMérieux of Grenoble, France. **DT**

Study: Air accurate acne info via Twitter

Boston — Dermatologists can use Twitter for insight into patient disease perceptions medical information to followers, a letter by Boston-based Center for Connected Health researchers suggests.

The researchers used real-time data capture via the Twitter Streaming Application Programming Interface (API) to gather tweets that contained at least one of five particular words: pimple, pimples, zit, zits, and acne for a two-week duration in June 2012. Researchers evaluated 8,192 English high-impact tweets (tweets with one or more retweets). The team judged language and content against the American Academy of Dermatology's acne information website.

There were four categories: personal, celebrity, education, and irrelevant/excluded. For education, there were subcategories: disease question, disease information, treatment question, and treatment information (branded, non-branded and ambiguous).

Personal tweets about acne were the most popular (43.1 percent); then tweets about celebrities (20.4 percent), followed by education-related tweets (27.1 percent); 9.4 percent of tweets were excluded. Two-thirds of disease question tweets asserted that stress causes pimples, and 9 percent of retweets commented that makeup causes pimples.

"Twitter is emerging as a popular forum where people exchange health information. Health providers can not only learn about the perceptions and misperceptions of diseases like acne, but they might also communicate reliable medical information," the authors wrote.

The findings were published in the May 15, 2013 issue of *JAMA Dermatology*. **DT**

WHAT CAN WE SAY?

THE LADIES LOVE US

TRI-LUMA® CREAM

Has Returned

The only FDA-approved triple-combination topical to treat moderate to severe melasma of the face is back.

Important Safety Information

Indication: TRI-LUMA® (fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%) Cream is indicated for the short-term (up to 8 weeks) treatment of moderate to severe melasma of the face in the presence of measures for sun avoidance, including the use of sunscreens. **Adverse Events:** In the controlled clinical trials, the most frequently reported events were redness, peeling, burning, dryness, and itching at the site of application. **Warnings/Precautions:** TRI-LUMA contains sulfites which may cause severe, life-threatening allergic reactions in people allergic to sulfites. TRI-LUMA contains hydroquinone, which may cause a gradual blue-black darkening of the skin. If you are pregnant, nursing or trying to become pregnant you should not use TRI-LUMA. Safety and efficacy have not been established in individuals with darker skin. Reversible HPA axis (adrenal function) suppression may result from exposure to the topical corticosteroid, fluocinolone acetonide, so discontinue use if signs and symptoms of this condition occur. Avoid products that may dry or irritate the skin, such as abrasive cleansers, scrubs, or skin-peeling agents. Exposure to sunlight, sunlamps, or UV light and extreme heat, wind, or cold should be avoided. If exposure cannot be avoided, sunscreen products [SPF 30 or more] and protective apparel should be used.

Tri-Luma® Cream

(fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of complete Prescribing Information on the following page.

Reference: 1. Balkrishnan R, Kelly AP, McMichael A, Torok H. Improved quality of life with effective treatment of facial melasma: the Pigment Trial. *J Drugs Dermatol.* 2004;3(4):377-381.

Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
TRI-585 Printed in USA 02/13

Learn more at www.triluma.com

GALDERMA
Committed to the future of dermatology

IMPORTANT INFORMATION ABOUT
TRI-LUMA® CREAM
(fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%)

BRIEF SUMMARY

This summary contains important information about TRI-LUMA (try-LOOM-ah) Cream. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using TRI-LUMA Cream. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about TRI-LUMA Cream. For full Prescribing Information and Patient Information see the package insert.

WHAT IS TRI-LUMA CREAM?

TRI-LUMA Cream is a medicine with three active components. You put TRI-LUMA Cream on your face to treat a skin condition called melasma. Melasma consists of dark (hyperpigmented) spots on facial skin, especially on the cheeks and forehead. This condition usually happens with hormone changes. TRI-LUMA Cream is for **SHORT-TERM (up to 8 weeks)** treatment of **moderate to severe** melasma of the face. **TRI-LUMA Cream may improve your melasma, but is NOT a cure.**

WHO IS TRI-LUMA CREAM FOR?

TRI-LUMA Cream is for use in adults. The safety and effectiveness of TRI-LUMA Cream in pediatric patients has not been established. Do **not** use TRI-LUMA Cream if you are allergic to the medicine or any of its ingredients.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING TRI-LUMA CREAM?

If you are pregnant, think you are pregnant, plan to be pregnant or are nursing an infant, tell your doctor. Your doctor will decide with you whether the benefits in using TRI-LUMA Cream will be greater than the risks. If possible, delay treatment with TRI-LUMA Cream until after the baby is born. Tell your doctor about all the medicines and skin products you use, including prescription and nonprescription medicines, cosmetics, and supplements. They may make your skin more sensitive to sunlight.

WHAT SHOULD I AVOID WHILE USING TRI-LUMA CREAM?

- **Sunlight or ultraviolet light.** TRI-LUMA Cream can make your skin more likely to sunburn or develop other unwanted effects from the sun. Staying out of the sun is especially important for women who take birth control pills or hormone replacement therapy and for people who have had dark patches in the past.
- Use an effective sunscreen with an SPF of 30 or more **anytime you** are outside, even on hazy days.
- Weather extremes, such as **heat, wind and cold**, may irritate the skin of patients using TRI-LUMA Cream.
    - Avoid products that may dry or irritate skin including soaps and cleaners that are rough or cause drying, certain astringents, such as alcohol-containing products, soaps and toiletries containing alcohol, spices or lime, certain medicated soaps, shampoos, and hair permanent products.

      Do not use any other medicines with TRI-LUMA Cream unless you have consulted with your doctor.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF TRI-LUMA CREAM?

The most common side effects associated with use of TRI-LUMA Cream are redness, peeling, burning, dryness, or itching.

A very few patients may get severe allergic reactions from TRI-LUMA. This includes people allergic to sulfites. **They may have trouble breathing or severe asthma attacks, which can be life-threatening.**

Some patients using TRI-LUMA develop dark spots on their skin (hyperpigmentation), tingling, increased skin sensitivity, rash, acne, skin redness caused by a condition called rosacea, skin bumps, blisters, or tiny red lines or blood vessels showing through the skin (telangiectasia).

Stop using TRI-LUMA Cream and contact your doctor if you have:

- severe or continued irritation, blistering, oozing scaling, or crusting.
- severe burning or swelling of your skin.
- irritation of your eyes, nose, and mouth.

HOW SHOULD I USE TRI-LUMA CREAM?

- TRI-LUMA Cream should be used as instructed by your doctor.
- Gently wash your face with a mild cleanser, using just your fingers. Rinse and pat dry.
- Unless you have been instructed otherwise, put a small amount (pea sized or less) on your fingertip. Next, apply a thin coat onto the discolored spot(s), at least 30 minutes before bedtime. Include about ½ inch of normal skin surrounding the affected area.
- Rub the medicine lightly and uniformly into your skin. The medicine should become invisible almost at once. If you can still see it, you are using too much.
- Keep the medicine away from the corners of your nose, mouth, eyes and open wounds.
- **Do not** use more TRI-LUMA Cream or apply it more often than recommended by your doctor. Too much TRI-LUMA Cream may irritate your skin, waste medicine, and won't give you faster or better results.
- Do not cover the treated area with anything after applying TRI-LUMA Cream.
- You may use a moisturizer and cosmetics during the day.
- Use a sunscreen of at least SPF 30 and a wide-brimmed hat over the treated areas. It requires only a small amount of sunlight to worsen melasma.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT TRI-LUMA CREAM?

- Talk to your doctor or pharmacist
- Go to www.triluma.com or call 1-866-735-4137

GALDERMA LABORATORIES, L.P. Fort Worth, Texas 76177 USA
Revised: January 2013
P52091-0-BS

GALDERMA
Committed to the future of dermatology

Tri-Luma® Cream
(fluocinolone acetonide 0.01%, hydroquinone 4%, tretinoin 0.05%)

ABSTRACTS FROM THAT PILE OF PEER-REVIEWED JOURNALS ON YOUR DESK

Research stat

CLINICAL DERMATOLOGY

Check cardiac risks in patients with long-lasting psoriasis

Scientific World Journal APRIL 2013

DERMATOLOGISTS SHOULD CONSIDER referring patients with long-lasting psoriasis for cardiovascular evaluation.

Researchers in Turkey focused on rhythm abnormalities and conduction disturbances in psoriatic patients due to the connection between psoriasis and markers of systemic inflammation, which, along with electrocardiographic markers and oxidative stress, have been implicated in the pathogenesis of atrial fibrillation.

The researchers physically examined 94 outpatients with psoriasis and 51 healthy patients. In addition, patients underwent transthoracic echocardiography examinations and 12-lead electrocardiograph, which were manually measured. Psoriasis severity was determined by psoriasis area and severity index (PASI).

The researchers found that both P wave dispersion (PWD) and QT interval dispersion (QTcD) were increased in psoriasis patients compared to healthy patients and significantly correlated with disease duration ($r = 0.693$, $P < 0.001$, and $r = 0.368$, $P = 0.003$, respectively). PWD is the most important ECG marker used to evaluate the risk of atrial arrhythmias, according to the report. Prolonged P wave duration and increased dispersion have been linked with higher risk for AF. QTD aids in assessing homogeneity of cardiac repolarization and may be a risk for ventricular arrhythmias, the authors wrote. Patients with psoriasis also had significantly longer transmitral deceleration time and isovolumetric relaxation time.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3628657

Underlying genetic mutation may cause port-wine stains

New England Journal of Medicine MAY 2013

RESEARCHERS HAVE IDENTIFIED the underlying genetic mutation responsible for port-wine stains and Sturge-Weber syndrome (SWS), which may allow for the development of more targeted therapies, according to investigators with Kennedy Krieger Institute, Baltimore.

The researchers identified the somatic mutation responsible for SWS and port-wine stains after performing whole genome sequencing on affected and unaffected tissue and blood samples from three patients with SWS. A nucleotide transition in gene GNAQ on chromosome 9q21 was shared by all three affected samples. The researchers confirmed their finding by detecting this mutation in 23 of 26 tissues samples from patients with SWS and in 12 of 13 samples from patients with port-wine stains.

The six control samples, four tissue samples from participants with an unrelated cerebrovascular malformation and 99.3 percent of exomes from the 1,000 Genomes database (664 of 669 exomes) were all negative, the authors reported. Analyses also revealed that the gene involved in SWS is the same gene implicated in uveal melanoma.

Scientists from Duke University Medical Center, Durham, N.C., collaborated in the study which further found that GNAQ encodes a set of membrane proteins that ensure signaling pathways within the cell work properly.

The revelation that SWS is caused by a somatic mutation enabled investigators to confirm that the syndrome is not inherited. The study findings should also allow researchers to begin looking into drugs that selectively inhibit implicated pathways.

http://www.nejm.org/doi/full/10.1056/NEJMoa1213507#t=abstract

Cleaning pacifiers with spit decreases later risk of eczema

Journal of Drugs in Dermatology MAY 2013

PARENTS WHO CLEAN THEIR CHILD'S PACIFIER with their own saliva may reduce their child's likelihood of developing eczema and allergies, researchers in Sweden report.

The researchers found that a parent's saliva introduces gut microflora onto the pacifier that, in turn, stimulates an infant's immune system against eczema, allergies and asthma. Oral bacteria are transferred on the pacifier from the parent's mouth to the baby's mouth and swallowed, which subsequently affects the microbiota in the child's small intestine and regulates tolerance development in the gut.

Among 136 babies who used a pacifier during their first six months of life, 65 had parents who reported sucking on the pacifiers to clean them. When the children were 18 months old, researchers found that the likelihood of both eczema and asthma were reduced in the children whose parents had used saliva to clean the pacifiers when compared with children whose parents did not clean the pacifiers this way. The protective effect held for eczema through age 36 months.

The study also found that spit-cleaning the pacifiers had no effect on transmission of respiratory illnesses from parents to children.

Researchers said that parents could choose instead to clean their baby's pacifier with soap and water or by boiling it; however, they recommend that parents lick the pacifier if their child was born through cesarean delivery. These children are more likely to develop allergies because they do not receive the immune system-boosting gut microbes that babies born vaginally receive when they pass through the birth canal.

http://pediatrics.aappublications.org/content/early/2013/04/30/peds.2012-3345.abstract

Novel compound reveals potent antifungal activity

International Journal of Dermatology APRIL 2013

A LEADING COMPOUND in a new class of antimicrobials has shown its efficacy in the treatment of dermatophytosis, researchers from Case Western Reserve School of Medicine in Cleveland and colleagues report.

The researchers evaluated the activity of topical formulations of NVC-422 (sodium 2-[dichloroamino]-2-methylpropane-1-sulfonate) using an experimental guinea pig model. Guinea pigs infected with *Trichophyton mentagrophytes* were randomly assigned to four treatment and two control groups. Each group began treatment 72 hours after infection. The animals were treated three times a day for seven days with either 0.5 percent NVC-422 in 0.5 percent Noveon gel, 1 percent NVC-422 in 1 percent Noveon gel, 1.5 percent NVC-422 in 1 percent Noveon gel or 2 percent NVC-422 in 1 percent Noveon gel. One control group received 1 percent Noveon gel, while the other was untreated. Treatment efficacy was assessed 72 hours after the final topical dose.

Researchers noted that while each treatment group showed statistically significant clinical and mycological efficacy, with 80 percent to 98 percent of animals demonstrating mycological cure, the highest degree of clinical and mycological efficacy was shown in the group of animals treated with 2 percent NVC-422 in 1 percent Noveon gel.

Researchers detected fungal elements in skin sections from untreated guinea pigs but not in the skin sections gathered from animals in each of the treatment groups.

NVC-422 appears to have potent antifungal activity *in vivo,* the researchers wrote; therefore, it should be the focus of further clinical evaluation for the treatment of superficial fungal infections.

http://onlinelibrary.wiley.com/doi/10.1111/j.1365-4632.2012.05477.x/abstract

RESEARCH STAT see page 22

ResearchSTAT

ABSTRACTS FROM THAT PILE OF PEER-REVIEWED JOURNALS ON YOUR DESK

RESEARCH STAT from page 21

Evening primrose oil ineffective for eczema

The Cochrane Library
APRIL 2013

A REVIEW OF THERAPEUTIC alternatives for the treatment of eczema revealed that evening primrose oil and borage oil don't have an effect on the condition.

Researchers with the University of Minnesota, Duluth, searched national databases, online trial registers and unpublished and ongoing trials. They analyzed 1,596 participants in 27 studies. Among the studies, 19 assessed evening primrose oil (EPO) and eight assessed borage oil, according to the abstract. A meta-analysis of results from seven EPO studies demonstrated EPO did not significantly increase improvement in global eczema symptoms as reported by the participants on a visual analogue scale of 0 to 100 and a visual analogue scale of 0 to 100 for medical doctors, compared to the placebo group.

Although a meta-analysis was not conducted for studies focused on the use of BO due to the difference in how the studies were reported, the researchers' assessment demonstrated that BO did not significantly improve global eczema symptoms compared to placebo treatment as reported by both participants and medical doctors, the abstract notes.

The researchers noted similar mild, temporary side-effects, which were mainly gastrointestinal. The study did not look at long-term use of the products.

Due to narrow confidence intervals, the authors concluded that it would be difficult to justify further studies on EPO or BO for eczema.

http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004416.pub2/abstract

PEDIATRIC DERMATOLOGY

Skin reaction times vary with food allergies

Nutrition Research and Practice
APRIL 2013

THE TIME TO ONSET OF ATOPIC DERMATITIS from food allergies ranges widely, a study shows.

Researchers at Hanyang University, Seojeong College, and Chungnam National University Hospital assessed 2,417 patients with atopic dermatitis (AD) over 10 years. Each patient underwent blood, skin-prick, and food challenge tests.

About half of the patients with AD displayed non-IgE-mediated, IgE-mediated, or mixed allergies food allergies (n = 1,225) to eggs, milk, wheat, soybeans, chicken, pork or beef. The total number of reactions to different food items varied. The most commonly seen combination in patients with two food allergies was eggs and milk.

The most severe reactions were to wheat, followed by beef, soybeans, milk, pork, eggs, and chicken. The onset times of food allergy reactions varied from 0.2-24 hours for wheat, 0.5-48 hours for beef, 1.0-24 hours for soybeans, 0.7-24 hours for milk, 3.0-24 hours for pork, 0.01-72 hours for eggs, and 3.0-72 hours for chicken. The authors note that future studies should include a broader range of foods to establish dietary guidelines, and add that identifying food allergies may help to improve chronic AD symptoms.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3627928/

Medicaid-insured children have limited access to dermatology

Journal of the American Academy of Dermatology MAY 2013

CHILDREN WITH ECZEMA who are insured through Medicaid have limited access to dermatologists, a recent study found.

Researchers at the Saint Louis University School of Medicine, St. Louis, Mo., surveyed 13 metropolitan areas by calling dermatologists listed in Medicaid health plans. Two calls were made to each office in which a researcher posed as a parent requesting an appointment for a child with eczema. In one call, the researcher claimed to have Medicaid. The researchers attempted to contact 723 offices resulting in 471 dermatology practices being included in the final analysis. Although wait times did not vary significantly between insurance types, the researchers found that nearly half (44 percent) of the offices refused to see a new Medicaid patient.

The researchers stressed that the number of doctors who take Medicaid patients is dynamic. The confirmed appointment sample sizes were limited due to the lack of identification numbers and referrals.

http://www.jaad.org/article/S0190-9622(12)01169-3/abstract

COSMETIC DERMATOLOGY

Platelet-rich plasma solution could be hair growth solution

British Journal of Dermatology APRIL 2013

A PLATELET-RICH PLASMA (PRP) solution may be a safe and effective treatment option for alopecia areata (AA), according to study findings.

Researchers at the University of Brescia, Brescia, Italy, and colleagues randomly assigned 45 patients with AA to receive intra-lesional injections of PRP, triamcinolone acetonide (TrA), or placebo on one half of their scalp, according to the abstract. The other half of the scalp was untreated. Each patient received three treatments monthly.

Researchers then assessed hair regrowth, hair dystrophy, burning and itching, as well as cell proliferation in each patient for one year.

The researchers noted a significant increase in cell proliferation markers and hair regrowth, as well as decreased hair dystrophy and burning and itching in patients treated with PRP compared with TrA or placebo, according to the abstract. There were no reported side effects.

The researchers call for more extensive controlled studies.

http://onlinelibrary.wiley.com/doi/10.1111/bjd.12397/abstract

ONCOLOGY

Squamous cell skin cancers deadly for some patients

JAMA Dermatology MAY 2013

CUTANEOUS SQUAMOUS CELL CARCINOMAS typically are easily cured with surgery or ablation, but in certain patients with disease risk factors, the cancer can result in death, according to study findings.

Investigators with Harvard University, Cambridge, Mass., reviewed cases of 1,832 squamous cell carcinoma tumors among 985 patients in a 10-year retrospective study. Among the patients, 3.7 percent developed nodal metastases and 2.1 percent died as a result of the disease, according to the study abstract.

The independent predictors for nodal metastasis and disease-specific death included a tumor diameter of at least 2 cm, invasion beyond fat, and ear or temple location. Perineural invasion also was associated with disease-specific death. Study authors noted that knowledge of associated risk factors could help to select an appropriate treatment in earlier disease stages.

http://archderm.jamanetwork.com/article.aspx?articleid=1688089&atab=7

NEW

Unilever

DOVE® MEN+CARE®

NEW HYDRATE + FACE LOTION

HELP YOUR MALE PATIENTS GET THE MOISTURE THEIR SKIN NEEDS

It's not always easy to get men to use certain skin care products. That's why Dove® Men+Care™ has introduced a new face care line to encourage men to take better care of their skin.

New Dove® Men+Care™ Hydrate + Face Lotion provides advanced protection for dry skin. It helps lock in moisture, keeping men's skin hydrated all day.

- +Broad-spectrum SPF 15
- +Fast absorbing
- +Non-greasy solution
- +Noncomedogenic
- +Hypoallergenic

Recommend Dove® Men+Care™—Designed for His Skin Care Needs

doveprofessional.com/men

ROSACEA refinements

Disease management eases as newer treatments emerge

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — The treatment of rosacea is becoming increasingly patient-friendly, according to an expert.

In particular, says Frank C. Powell, M.D., "The treatment of rosacea has been refined in recent years." Dr. Powell, a consultant dermatologist at the Charles Institute of Dermatology, University College Dublin, Ireland, spoke at the American Academy of Dermatology annual meeting.

The current approach begins with either topical or systemic antibiotics, depending on disease severity, he says. For highly inflamed, active disease, "We usually start with systemic antibiotics — such as minocycline, erythromycin and doxycycline — to cool down the skin."

QUICK READ

Newer treatments for rosacea include low-dose doxycycline, low-dose isotretinoin and a topical brimonidine gel awaiting FDA approval, an expert says.

Additionally, Dr. Powell says the advent of low-dose doxycycline has advanced the treatment of rosacea. Specifically, he says, a dose of 40 mg daily normally wouldn't have an antibacterial effect. The fact that it works for rosacea suggests it does not kill bacteria, but it provides anti-inflammatory or other as-yet recognized effects, he says. Thanks to the clinical efficacy and cost-effectiveness of low-dose doxycycline for rosacea, he adds, it's popular among physicians and patients.

Systemic antibiotics also work for the ocular inflammation of rosacea, Dr. Powell says. "Additionally, one can use topical metronidazole in the eyelashes. And a topical cyclosporine gel has been effective for the ocular lesions of rosacea." He prescribes systemic antibiotic treatments for a period of six to eight weeks, he adds, versus the four months or more of treatment required for patients with acne.

Exploring isotretinoin

"Another drug that is sometimes used in the management of severe cases of rosacea that are unresponsive to systemic antibiotics is isotretinoin," Dr. Powell says.

In this regard, he says, "We must be careful in patients with rosacea because isotretinoin's drying effects on the lips, eyes and skin are poorly tolerated by these patients, who already tend to dryness of the skin. So we use a low-dose isotretinoin treatment, approximately 20 mg daily (Uslu M, Şavk E, Karaman G, Şendur N. *Acta Derm Venereol.* 2012;92(1):73-77)." This dose provides efficacy, he says, "But unfortunately, when the treatment stops, these patients usually relapse, but their rosacea is often not as severe as previously." In the study cited above, 45 percent of patients relapsed within 11 months' follow-up.

Topical maintenance

In managing rosacea, Dr. Powell says, "Remember that it's a chronic condi-

ROSACEA REFINEMENTS see page 27

Quotable

"Remember that it's a chronic condition — it tends to remit and relapse."

Frank C. Powell, M.D.
Dublin, Ireland

on treating rosacea

See story, page 27

PDL improves QOL for rosacea patients

DT Extra Pulsed dye laser treatment may improve the quality of life for some rosacea patients, according to a study published online in *The Journal of Clinical and Aesthetic Dermatology.* Researchers used the Dermatology Life Quality Index questionnaire before and after laser treatment to assess symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Researchers found that PDL had a positive effect in all six subcategories of the DLQI index, noting that the improvement was statistically significant. Four of 20 patients reported a DLQI score of 0 (without any effect on quality of life) post-laser therapy.

Source: *The Journal of Clinical and Aesthetic Dermatology*

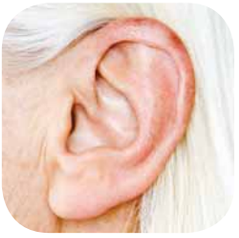
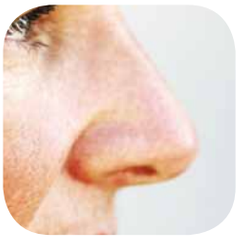
High Clearance[1*]

Low Down Time[†]

Monitored Completion[**]

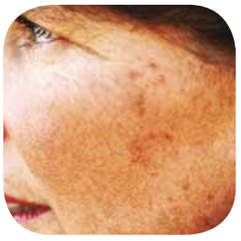
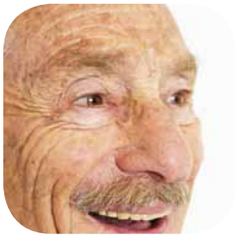
Few AKs

Localized area | Sensitive area | Larger area


Multiple AKs

Localized area | Larger area

The Levulan® Kerastick® for Topical Solution plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp.

*At 8 weeks, 77% of patients treated with Levulan PDT experienced 75% clearance of AK lesions vs 23% of the control group. 83% of the patients treated with Levulan PDT had 75% clearance of face lesions and 60% of the patients had 75% clearance of scalp lesions. 66% of patients treated with Levulan PDT experienced 100% clearance of AK lesions vs 13% of the control group. 70% of the patients treated with Levulan PDT had 100% clearance of face lesions and 55% of the patients had 100% clearance of scalp lesions.

*Results from two identical, randomized, multi-center, two-arm Phase 3 studies with a total of 243 patients. Patients who were not complete responders at week 8 had a retreatment of the persistent target lesions. All patients returned at week 12 after initial treatment.

†Patients treated with Levulan PDT should avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours.

**Levulan PDT is a 2-part treatment procedure that can be completed within a 24 hour period.

Important Risk Information

Application of Levulan Kerastick should involve either scalp or face lesions, but not both simultaneously. Levulan Kerastick should not be applied to the periorbital area or allowed to contact ocular or mucosal surfaces. Excessive irritation may be experienced if this product is applied under occlusion.

Contraindicated in patients with cutaneous photosensitivity at wavelengths of 400-450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the Levulan Kerastick for Topical Solution. Levulan Kerastick has not been tested on patients with inherited or acquired coagulation defects.

Transient local symptoms of stinging and/or burning, itching, erythema, and edema were observed in all clinical studies. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during treatment. However, less than 3% of patients discontinued light treatment due to stinging and/or burning. The most common adverse events include scaling/crusting, hypo/hyperpigmentation, itching, stinging and/or burning, erythema and edema. In 99% of active treatment patients, some or all lesions were erythematous shortly after treatment, while in 79% of vehicle-treated patients, some or all lesions were erythematous. In 35% of active treatment patients, some or all lesions were edematous, while no vehicle-treated patients had edematous lesions.

Please see safety information on adjacent page.

1. Levulan® Kerastick® Prescribing Information. DUSA Pharmaceuticals, Inc.®

Levulan® Kerastick®
(aminolevulinic acid HCl)
for Topical Solution, 20%

Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%
Initial U.S. approval: 1999

INDICATIONS AND USAGE

The LEVULAN KERASTICK for Topical Solution, a porphyrin precursor, plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp.

CONTRAINDICATIONS

The LEVULAN KERASTICK for Topical Solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is contraindicated in patients with cutaneous photosensitivity at wavelengths of 400-450 nm, porphyria or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK for Topical Solution.

WARNINGS AND PRECAUTIONS

Photosensitivity

During the time period between the application of LEVULAN KERASTICK Topical Solution and exposure to activating light from the BLU-U Blue Light Photodynamic Therapy Illuminator, the treatment site will become photosensitive. After LEVULAN KERASTICK Topical Solution application, patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) during the period prior to blue light treatment. Exposure may result in a stinging and/or burning sensation and may cause erythema and/or edema of the lesions. Before exposure to sunlight, patients should, therefore, protect treated lesions from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material. Sunscreens will not protect against photosensitivity reactions caused by visible light. It has not been determined if perspiration can spread the LEVULAN KERASTICK Topical Solution outside the treatment site to eye or surrounding skin.

Application of LEVULAN KERASTICK Topical Solution to perilesional areas of photodamaged skin of the face or scalp may result in photosensitization. Upon exposure to activating light from the BLU-U Blue Light Photodynamic Therapy Illuminator, such photosensitized skin may produce a stinging and/or burning sensation and may become erythematous and/or edematous in a manner similar to that of actinic keratoses treated with LEVULAN KERASTICK Photodynamic Therapy. Because of the potential for skin to become photosensitized, the LEVULAN KERASTICK should be used by a qualified health professional to apply drug only to actinic keratoses and not perilesional skin. If for any reason the patient cannot return for blue light treatment during the prescribed period after application of LEVULAN KERASTICK Topical Solution (14 to 18 hours), the patient should call the doctor. The patient should also continue to avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours. If stinging and/or burning is noted, exposure to light should be reduced.

Irritation

The LEVULAN KERASTICK Topical Solution contains alcohol and is intended for topical use only. Do not apply to the eyes or to mucous membranes. Excessive irritation may be experienced if this product is applied under occlusion.

Coagulation Defects

The LEVULAN KERASTICK for Topical Solution has not been tested on patients with inherited or acquired coagulation defects.

ADVERSE REACTIONS

In Phase 3 studies, no non-cutaneous adverse events were found to be consistently associated with LEVULAN KERASTICK Topical Solution application followed by blue light exposure.

Photodynamic Therapy Response: The constellation of transient local symptoms of stinging and/or burning, itching, erythema and edema as a result of LEVULAN KERASTICK Topical Solution plus BLU-U treatment was observed in all clinical studies of LEVULAN KERASTICK for Topical Solution Photodynamic Therapy for actinic keratoses treatment. Stinging and/or burning subsided between 1 minute and 24 hours after the BLU-U Blue Light Photodynamic Therapy Illuminator was turned off, and appeared qualitatively similar to that perceived by patients with erythropoietic protoporphyria upon exposure to sunlight. There was no clear drug dose or light dose dependent change in the incidence or severity of stinging and/or burning.

In two Phase 3 trials, the sensation of stinging and/or burning appeared to reach a plateau at 6 minutes into the treatment. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of the patients at some time during treatment. The majority of patients reported that all lesions treated exhibited at least slight stinging and/or burning. Less than 3% of patients discontinued light treatment due to stinging and/or burning.

In the Phase 3 trials, the most common changes in lesion appearance after LEVULAN KERASTICK for Topical Solution Photodynamic Therapy were erythema and edema. In 99% of active treatment patients, some or all lesions were erythematous shortly after treatment, while in 79% of vehicle treatment patients, some or all lesions were erythematous. In 35% of active treatment patients, some or all lesions were edematous, while no vehicle-treated patients had edematous lesions. Both erythema and edema resolved to baseline or improved by 4 weeks after therapy. LEVULAN KERASTICK Topical Solution application to photodamaged perilesional skin resulted in photosensitization of photodamaged skin and in a photodynamic response (see Warnings and Precautions).

Other Localized Cutaneous Adverse Experiences: Table 1 depicts the incidence and severity of cutaneous adverse events in Phase 3 studies, stratified by anatomic site treated.

TABLE 1 Post-PDT Cutaneous Adverse Events - ALA-018/ALA-019

	FACE				SCALP			
	LEVULAN (n=139)		Vehicle (n=41)		LEVULAN (n=42)		Vehicle (n=21)	
Degree of Severity	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe
Scaling/Crusting	71%	1%	17%	0%	64%	2%	19%	0%
Pain	1%	0%	0%	0%	0%	0%	0%	0%
Tenderness	1%	0%	0%	0%	2%	0%	0%	0%
Itching	23%	1%	7%	0%	14%	7%	19%	0%
Edema	1%	0%	0%	0%	0%	0%	0%	0%
Ulceration	4%	0%	0%	0%	2%	0%	0%	0%
Bleeding Hemorrhage	4%	0%	0%	0%	2%	0%	0%	0%
Hypo/hyper-pigmentation	22%		20%		36%		33%	
Vesiculation	4%	0%	0%	0%	5%	0%	0%	0%
Pustules	4%	0%	0%	0%	0%	0%	0%	0%
Oozing	1%	0%	0%	0%	0%	0%	0%	0%
Dysesthesia	7%	0%	0%	0%	0%	0%	0%	0%
Scabbing	2%	1%	0%	0%	0%	0%	0%	0%
Erosion	14%	1%	0%	0%	2%	0%	0%	0%
Excoriation	1%	0%	0%	0%	0%	0%	0%	0%
Wheal/Flare	2%	1%	0%	0%	2%	0%	0%	0%
Skin disorder NOS	3%	0%	0%	0%	12%	0%	5%	0%

Adverse Experiences Reported by Body System: In the Phase 3 studies, 7 patients experienced a serious adverse event. All were deemed remotely or not related to treatment. No clinically significant patterns of clinical laboratory changes were observed for standard serum chemical or hematologic parameters in any of the controlled clinical trials.

OVERDOSAGE

LEVULAN KERASTICK Topical Solution Overdose

LEVULAN KERASTICK Topical Solution overdose has not been reported. In the unlikely event that the drug is ingested, monitoring and supportive care are recommended. The patient should be advised to avoid incidental exposure to intense light sources for at least 40 hours after ingestion. The consequences of exceeding the recommended topical dosage are unknown.

BLU-U Light Overdose

There is no information on overdose of blue light from the BLU-U Blue Light Photodynamic Therapy Illuminator following LEVULAN KERASTICK Topical Solution application.

Information for Patients:
LEVULAN KERASTICK Photodynamic Therapy for Actinic Keratoses.

- The first step in LEVULAN KERASTICK Photodynamic Therapy (PDT) for actinic keratoses is application of the LEVULAN KERASTICK Topical Solution to actinic keratoses located on the patient's face or scalp.
- After LEVULAN KERASTICK Topical Solution is applied to the actinic keratoses in the doctor's office, the patient will be told to return the next day. During this time the actinic keratoses will become sensitive to light (photosensitive). Care should be taken to keep the treated actinic keratoses dry and out of bright light. After LEVULAN KERASTICK Topical Solution is applied, it is important for the patient to wear light-protective clothing, such as a wide-brimmed hat, when exposed to sunlight or sources of light.
- Fourteen to eighteen hours after application of LEVULAN KERASTICK Topical Solution the patient will return to the doctor's office to receive blue light treatment, which is the second and final step in the treatment. Prior to blue light treatment, the actinic keratoses will be rinsed with tap water. The patient will be given goggles to wear as eye protection during the blue light treatment.
- The blue light is of low intensity and will not heat the skin. However, during the light treatment, which lasts for approximately 17 minutes, the patient will experience sensations of tingling, stinging, prickling or burning of the treated lesions. These feelings of discomfort should improve at the end of the light treatment.
- Following treatment, the actinic keratoses and, to some degree, the surrounding skin, will redden, and swelling and scaling may also occur. However, these lesion changes are temporary and should completely resolve by 4 weeks after treatment.

US Patents: 5,079,262 5,211,938 5,954,703,
Manufactured for: DUSA Pharmaceuticals, Inc.®
25 Upton Drive, Wilmington, MA 01887

For more information please contact: 1-877-533-3872 or 1-978-657-7500
www.dusapharma.com

LAB-1442AW Rev A

DUSA®

ROSACEA REFINEMENTS:

Newer therapies aid disease management from page 24

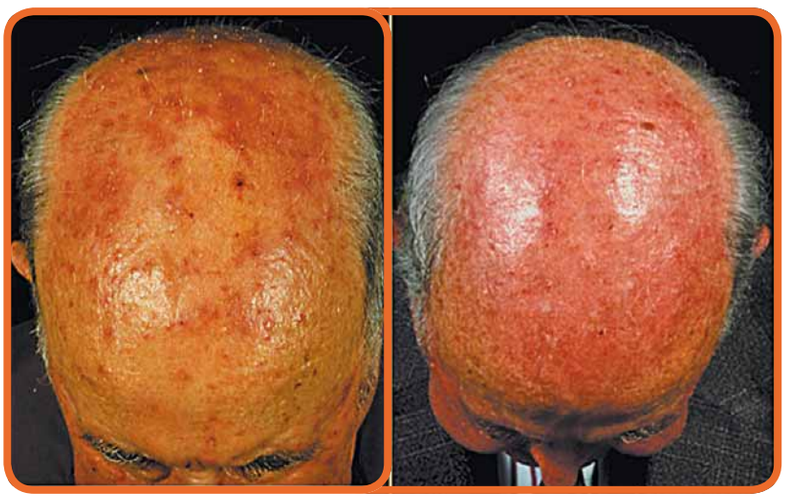
tion — it tends to remit and relapse. So patients will have to reintroduce treatment from time to time. And some patients require maintenance treatment with topical agents such as metronidazole or azelaic acid on a consistent basis. The majority will be able to stop treatment for a period, but they'll have to be advised to reintroduce the treatment when the condition relapses."

Conversely, he says that for moderate rosacea, the most commonly used effective topical treatments include metronidazole and azelaic acid 15 percent, both of which are available in cream or gel formulations. Applied twice daily for a period of approximately six weeks, "They are both very effective at providing remissions of rosacea. There are other topical agents that are also effective but less frequently used in this condition."

For the redness of rosacea, Dr. Powell says, topical brimonidine gel provides a new approach. Although he hasn't prescribed it, "The literature suggests that it's very effective in reducing erythema, which patients find very troublesome and annoying."

In a phase 2 study, a single application of topical brimonidine tartrate gel 0.5 percent achieved a significant improvement in redness reduction over vehicle between 30 minutes and 12 hours post-application. In a second phase 2 study published simultaneously, brimonidine 0.5 percent once daily showed a statistically superior success profile versus vehicle on follow-up days one, 15 and 29 (Fowler J, Jarratt M, Moore A, et al. *Br J Dermatol.* 2012;166(3):633-641). Once-daily brimonidine gel 0.5 percent also met its clinical endpoints in a pivotal phase 3 trial for rosacea.

Regarding side effects of medications used for rosacea, Dr. Powell says that outside of isotretinoin, "The other medications tend to be very well-tolerated. The side effect profile is similar to that in acne for this group of medications."



A 65-year-old male patient before and after six weeks of minocycline therapy. (Photos: Frank C. Powell, M.D.)

> "We must be careful in patients with rosacea because **isotretinoin's drying effects** on the lips, eyes and skin **are poorly tolerated** by these patients."
>
> **Frank C. Powell, M.D.**
> Dublin, Ireland

Pregnancy gives pause

As a caveat, he adds that for pregnant women with rosacea, "We do not like to use systemic antibiotic treatment if we can avoid it. However, erythromycin can be given in a dose of 500 mg daily. That appears to be safe, from the obstetricians' point of view."

By the same token, Dr. Powell says that a topical erythromycin solution appears safe in pregnancy. DT

Disclosure: University College Dublin recently signed an agreement with Galderma to fund a research module on rosacea in Dr. Powell's laboratory. No funds had been provided at press time. Dr. Powell receives and has received no personal funding from external interests.

CLUED IN

Studies yield clues to pathology, treatment of rosacea

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — New knowledge regarding rosacea's pathology may explain why some newer treatment strategies appear effective, while pointing the way for additional approaches, according to an expert who spoke at the American Academy of Dermatology's annual meeting.

Among the most exciting developments in researchers' understanding of rosacea is the recently reported neurogenic subtype of rosacea, says Frank C. Powell, M.D., a consultant dermatologist at the Charles Institute of Dermatology, University College Dublin, Ireland.

"Topical brimonidine gel is a vasoconstrictor that studies have shown is effective in the management of the erythema associated with rosacea."

Frank C. Powell, M.D.
Dublin, Ireland

In this regard, he says, several studies suggest that this new subtype features the release of neurotransmitters in the skin (Scharschmidt TC, Yost JM, Truong SV, et al. *Arch Dermatol.* 2011;147(1):123-126).

Also intriguing is the question of how neurogenic rosacea interacts with the skin's blood vessels to produce erythema and flushing, he says.

"It is postulated that neurotransmitters lead to vasodilatation in the skin, and the release of neurotransmitters that cause stinging and burning," Dr. Powell says.

Additionally, research has shown that administering pituitary adenylate cyclase-activating polypeptide (PACAP), a neuropeptide which helps regulate blood vessels, into the skin causes flushing, swelling and itching (Schwab VD, Sulk M, Seeliger S, et al. *J Investig Dermatol Symp Proc.* 2011;15(1):53-62). Therefore, Dr. Powell says, blocking PACAP may reduce redness and flushing in rosacea.

By the same token, he says, "Topical brimonidine gel is a vasoconstrictor that studies have shown is effective in the management of the erythema associated with rosacea. This further supports the concept of the neurogenic pathway of inflammatory erythema in rosacea."

Mites and more

Dr. Powell notes that recent research suggests that the innate immune system is hyperactive in the skin of patients with rosacea (Yamasaki K, Gallo RL. *J Investig Dermatol Symp Proc.* 2011;15(1):12-15; Yamasaki K, Gallo RL. *J Dermatol Sci.* 2009;55(2):77-81).

Furthermore, Dr. Powell says many studies substantiate that the population of *Demodex folliculorum* mites is greatly elevated in the skin of patients with rosacea. He poses the question whether the elevated mite population could be triggering the immune response in patients with rosacea.

"Studies show that anti-Demodex therapy achieves positive clinical results in those patients," he says. One such study involved 60 patients with resistant rosacea and high Demodex counts. They were randomized to treatment with either ivermectin or ivermectin and metronidazole. After four weeks, the proportions of patients in these groups who achieved complete remission were 45 percent and 71 percent, respectively (Salem DA, El-Shazly A, Nabih N, et al. *Int J Infect Dis.* 2013;17(5):e343-e347. Epub 2013 Jan 5).

Somewhat similarly, he says, "We ourselves have performed some studies showing that the mites can modify the immune response in patients with rosacea (Lacey N, Delaney S, Kavanagh K, Powell FC. *Br J Dermatol.* 2007;157(3):474-481. Epub 2007 Jun 26)."

In this regard, one study suggests that a defect in innate or induced immunity allows the proliferation of Demodex mites in the skin. When the mite population reaches critical levels, they cause trauma or breaches in the affected follicles of the face, which provokes an exaggerated immune response that can result in the formation of papules and pustules (Forton FM. *J Eur Acad Dermatol Venereol.* 2012;26(1):19-28).

CLUED IN see page 32

QUICK READ

New knowledge about neurogenic rosacea, as well as the role of genetics and Demodex mites, is pointing the way toward treatment options, an expert says.

From hard-to-reach spots to large body areas...

WE'VE GOT YOU COVERED

Available in
63 g and 100 g sizes

KENALOG®
SPRAY *with Spray Tube*
Triamcinolone Acetonide
Topical Aerosol, USP (0.147mg/g)

The Only Triamcinolone in an Aerosol Spray

- Formulation cools skin; decreases itch[1]
- Minimal ingredients -- vehicle contains isopropyl palmitate (a moisturizer); low dehydrated alcohol content
- No touch, precise application at any angle
- Delivers 0.2% triamcinolone*

RELIEF NEVER FELT SO GOOD

Indication:

Kenalog® Spray (triamcinolone acetonide topical aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Important Safety Information:

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

You are encouraged to report negative side effects of prescription drugs to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For topical use only. Please see adjacent page for full prescribing information.

For more information, visit www.kenalogspray.com

Reference:

1. Data on file. Ranbaxy Laboratories, Inc. Princeton, NJ.

***** After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

KS 1212

RANBAXY
Trusted medicines.Healthier lives

KENALOG® SPRAY

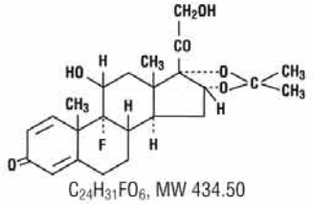
Rx only

Triamcinolone Acetonide Topical Aerosol, USP (0.147 mg/g)

For dermatologic use only
Not for ophthalmic use

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include triamcinolone acetonide. Triamcinolone acetonide is designated chemically as 9-fluoro-11β, 16α, 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17- acetal with acetone. The structural formula is:



$C_{24}H_{31}FO_6$, MW 434.50

A two-second application, which covers an area approximately the size of the hand, delivers an amount of triamcinolone acetonide not exceeding 0.2 mg. After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient

Patients using Kenalog Spray 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 and inhalation of the spray.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.
6. Do not use Kenalog Spray on the underarms or groin areas unless directed by your physician.
7. If no improvement is seen within 2 weeks, contact your physician.
8. Do not use other corticosteroid-containing products while using Kenalog Spray without first consulting your physician.
9. Kenalog Spray is flammable. Avoid heat, flames or smoking when applying Kenalog Spray.

Laboratory Tests

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy: Teratogenic Effects

Category C. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and 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.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS, General**).

DOSAGE AND ADMINISTRATION

Directions for use of the spray can are provided on the label. The preparation may be applied to any area of the body, but when it is sprayed about the face, care should be taken to see that the eyes are covered, and that inhalation of the spray is avoided.

Spray is flammable; avoid heat, flame or smoking when using this product.

Three or four applications daily of Kenalog Spray (Triamcinolone Acetonide Topical Aerosol) are generally adequate.

HOW SUPPLIED

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP)

63 g (NDC 10631-093-62) aerosol can.

100 g (NDC 10631-093-07) aerosol can.

Storage and Handling

Store at room temperature; avoid excessive heat. Contents under pressure; do not puncture or incinerate. Keep out of reach of children.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

RANBAXY
Jacksonville, FL 32257 USA

Revised August 2011

Printed in the USA DERM-3567-1212

AVOIDING IRRITATION

Treating acne, rosacea in patients of color requires attention to inflammation

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — Recent developments regarding acne and rosacea in skin of color include studies showing that combination topical products for acne appear safe in this population, and the fact that rosacea is perhaps more prevalent than many might expect.

In the former area, Valerie D. Callender, M.D., says some dermatologists and patients have wondered whether newer topical combination products for acne increase irritation in darker skin types. Dr. Callender, who spoke at the annual meeting of the American Academy of Dermatology, is associate professor of dermatology, Howard University College of Medicine, Washington, D.C., and a private practitioner based in the Washington metropolitan area.

In this regard, she says that when it comes to dual-combination products, "We've shown that the ingredients are safe when used as monotherapy." More recently, she says, research has shown that when one combines agents, "There's no increased risk of irritation."

Combination comparisons

In fact, a meta-analysis of three pivotal clinical trials involving benzoyl peroxide-adapalene combination treatments showed that these products tend to cause less erythema, scaling and dryness ($P<0.001$ in all three analyses) in skin types IV through VI than in skin types I through III (Callender VD, Preston N, Osborn C, et al. *J Clin Aesthet Dermatol*. 2010;3(8):15-19). Other studies have found no differences between these populations regarding tolerability of the following combinations:

Clindamycin-benzoyl peroxide (Callender VD. *J Drugs Dermatol*. 2012;11(5):643-648); and Clindamycin-tretinoin (Callender VD, Young CM, Kindred C, Taylor SC. *J Clin Aesthet Dermatol*. 2012;5(7):25-32).

The tolerability of these newer combination treatments stems largely from their use of water-based vehicles, rather than alcohol, Dr. Callender says.

"Some of the vehicles also contain moisturizers," she says.

Meanwhile, dermatologists' understanding of the role of inflammation in all acne is growing. Historically, she says, "We've thought about the acne lesion being either inflammatory or noninflammatory. But the new theory is that all lesions are inflammatory — that's how acne starts."

In one study, investigators biopsied apparently noninflammatory comedones in African-American patients. "But when the investigators looked at these lesions histologically, they found marked inflammation in the skin (Halder RM, Holmes YC, Bridgeman-Shah S, Kligman AM. *Invest Dermatol*. 1996;106:888; Abstract 495). So inflammatory lesions can include not just the papules, pustules, cysts and nodules, but also the comedones. This increases the risk of postinflammatory hyperpigmentation (PIH) in patients of color."

Moreover, she says that when treating patients of color with acne, "We must address the hyperpigmentation simultaneously. That's more important to the patient than the acne," which some of them may not know is causing the hyperpigmentation. "If you don't tell the patient you're treating the hyperpigmentation as well as the acne, the patient will not follow your regimen, because that's what they're complaining of — the dark spots." To that end, she recommends initiating topical

AVOIDING IRRITATION see page 32

QUICK READ

Evolving knowledge about skin of color includes the possibility that any acne lesion can contain inflammatory components, and the likelihood that rosacea occurs more often in darker skin than previously thought.

"Erythema and flushing are not readily seen in individuals with darker skin. So, as dermatologists, we must be more suspicious and look for other signs."

Valerie Callender, M.D.
Washington

CLUED IN:

New knowledge clears path for new rosacea treatment options from page 28

Inflammation reduction

Unlike in acne, Dr. Powell adds, "The inflammatory lesions that develop in people with rosacea are sterile. They don't tend to contain bacteria. Therefore, we believe that the antibiotics used in rosacea work by reducing inflammation rather than killing bugs."

Additionally, "There is a genetic predisposition toward rosacea" he says. "About 15 percent or more of people with rosacea have a family history of rosacea. It seems to be particularly common in Caucasians and those with a Celtic background (Chosidow O, Cribier B. *Ann Dermatol Venereol.* 2011;138 Suppl 3:S179-S183). It's very uncommon in people with darkly pigmented skin."

Research also shows that patients with rosacea have irregularities in their transient receptor potential ion channels of vanilloid type (TRPV). This is important because factors such as heat or topical capsaicin, which trigger rosacea symptoms and promote flushing, can activate TRPV channels, Dr. Powell says.

In one study, investigators used immunohistochemistry and other tests to show that patients with erythematotelangiectatic rosacea (subtype one) showed genetic expression of TRPV1, while the patients with papulopustular rosacea (subtype two) showed genetic expression of TRPV2 (Sulk M, Seeliger S, Aubert J, et al. *J Invest Dermatol.* 2012;132(4):1253-1262). Accordingly, these investigators write, TRP ion channels may be targets for the treatment of rosacea. Dr. Powell says that these genetic studies also could lend credence to the growing evidence suggesting that the different subtypes of rosacea may in fact be inherently different but related conditions. DT

Disclosure: Dr. Powell reports no relevant financial interests.

AVOIDING IRRITATION:

Acne, rosacea treatments in skin of color focus on inflammation from page 31

retinoid treatment at the first visit for all patients with acne because topical retinoids attack acne and PIH simultaneously.

> "The new theory is that **all lesions are inflammatory** — that's how acne starts."
>
> **Valerie Callender, M.D.**
> Washington

Use of hydroquinone

As for hydroquinone, she says that in the United States, exogenous ochronosis tends to result from continuous usage of over-the-counter hydroquinone for a decade or more. "It's very difficult to treat because you can't use hydroquinone for exogenous ochronosis." Several case reports explore the use of a 1,064 nm Q-switched Nd:YAG laser (at low settings) for this purpose, she says, but results in darker skin types are mixed.

Regarding rosacea, Dr. Callender adds, "The literature states that rosacea occurs mainly in Caucasians of European descent. There are very few case reports and is very little discussion about rosacea in patients of color. However, we do know that it exists in African-American, Hispanic, Indian and Asian populations. And it's important for dermatologists to know that. We need to publish more on rosacea in skin of color. Until then, we must teach each other that it does exist, and we must look for it" in this population.

In this regard, "Erythema and flushing are not readily seen in individuals with darker skin. So as dermatologists, we must be more suspicious and look for other signs." Whereas one must watch for PIH in patients of color with acne, she says, "In patients with darker skin types and rosacea, we see more hypopigmentation." The pathophysiology and treatment of rosacea are essentially the same regardless of skin type, Dr. Callender says, except that lasers and light-based devices have been shown to cause dyspigmentation in darker skin types. DT

Disclosure: Dr. Callender has been a consultant and speaker for Allergan, Galderma and Valeant, and a clinical investigator for Allergan, Galderma, Suneva and Medicis.

ONE COMPANY, *3 RESULTS DRIVEN SOLUTIONS!*

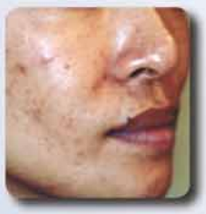
ADVANCED SKIN & HAIR INC.

Seen at AAD *American Academy of Dermatology*

Anti-DHT
ACNE TREATMENT

CLEAROGEN

Before

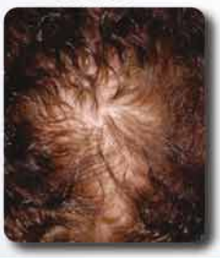


After 60 Days

Anti-DHT
HAIR LOSS TREATMENT

REVIVOGEN

Before



After 9 months

Growth Factor
ANTI-AGING TREATMENT

REJUVE MD

Before

After 28 Days

- **Natural Ingredients**
- **Proven Effective**
- **Real Results**

MEDICAL OFFICE WHOLESALE OFFERS

FREE LCD VIDEO DISPLAY
WITH OPENING ORDER $250 VALUE

- Lucrative Introductory Order
- Consistant Press Placements
- Complementary Quarterly Support Materials
- Free Samples

CALL OR EMAIL FOR PRICING AND SAMPLES!
SALESTEAM@REVIVOGEN.COM
(310) 442-9700

ADVANCED SKIN & HAIR INC.
12121 WILSHIRE BLVD STE 1012
LOS ANGELES, CA 90025

Dermatology Times

FAT advancements

Grafting technique improvements may give resurgence to aesthetic procedures

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — New advances in fat grafting techniques specifically focused on the way the fat is processed could result in a resurgence of the age-old cosmetic procedure, offering physicians a viable option to the popular synthetic fillers readily used.

Though fat grafting has always been considered to be an effective aesthetic tool used to replenish lost volume and correct contour deformities in cosmetic patients, the treatment modality has become somewhat eclipsed by the plethora of synthetic fillers often chosen by physicians in cosmetic procedures, such as hyaluronic acid fillers.

"Since the dawn of state-of-the-art synthetic fillers, fat grafting has often taken the backseat in corrective soft tissue filling procedures, in part due to the extra procedure required to harvest the fat," says Naomi Lawrence, M.D., head of the division of dermatology section of procedural dermatology, Cooper University Hospital, Marlton, N.J. "However, recent advances in fat grafting techniques can make the procedure the treatment of choice, particularly in those areas where a greater amount of filler is required for voluminization."

Dr. Lawrence

QUICK READ

New fat grafting techniques on the horizon could prove to be particularly useful in those cosmetic areas where a greater amount of filling is required.

Using less to do more

New technological advances being researched in the processing of the harvested fat may allow physicians to more effectively and efficiently use smaller amounts of fat because the harvested fat could survive longer than with older processing techniques, says Dr. Lawrence, who spoke at the annual meeting of the American Academy of Dermatology. Using innovative collagenase digestion techniques that disassociate the fat particles, smaller fat grafts could be transferred that revascularize better, increasing their potential for viability in the target area, she says.

The adipocyte stromal cells or stem cells can also be left in the mix, which could be partially differentiated and expanded once they are transferred to the target area. Moreover, the addition of factors that enhance the growth of both the fat and the stem cells could be added to the fat graft mix, Dr. Lawrence says, further increasing the potential viability of the fat grafts used.

"Fat grafting could be considered ideal for those areas where you really need a lot of filler, such as in those patients who have full-face lipoatrophy. Though numerous synthetic fillers can also be used for this cosmetic indication, eight to 10 syringes of product are often required to cosmetically correct the deformity, making fat grafting a much more desirable and economical treatment option," she says.

The perception of facial youthfulness is synonymous with fuller facial features such as a healthy and youthful looking plump cheek and temple areas. Many older cosmetic patients today are fit and have low body fat, but nevertheless

FAT ADVANCEMENTS see page 41

Quotable

"Complications from laser and light treatments are not uncommon."

Wendy Roberts, M.D.
Rancho Mirage, Calif.

on treating skin of color

See story, page 42

Topical CLP may improve elasticity, wrinkles

DT Extra Topical CLP (1-carbamimidoyl-L-prolin), an amino acid derivative, may be a promising skincare ingredient for targeting wrinkles. Researchers at Tokyo Women's Medical University evaluated 126 Japanese female patients who had crow's feet lines at 4 and 8 weeks after treatment according to authorized grades by the Japanese Cosmetic Science Society. More than half (57.8 percent) of patients treated with CLP had improved compared with 8.1 percent of patients given placebo lotion.

Source: *European Journal of Dermatology*

FAT ADVANCEMENTS:

Enhancements may result in more consistent outcomes from page 34

exhibit varying degrees of facial atrophy, resulting in a thin and drawn facial look. The volumizing required to correct the facial atrophy could ideally be done using fat grafting techniques, Dr. Lawrence says, as too much synthetic filler product would often be required to achieve this cosmetic goal.

Fat grafting indications

Much of the research in fat grafting is being performed outside of the United States, mostly because adipose stem cells isolated from mature fat are placed by the U.S. Food and Drug Administration in the drug category, Dr. Lawrence says, and most fat grafting research is focused around aesthetically filling the face.

Other areas where fat grafting techniques could be considered superior to synthetic fillers in terms of the sheer volume required to perform larger aesthetic corrections include the neck, breasts and the redundant skin around the knees. Another indication could be the atrophy typically seen in the aging dorsum of the hands, Dr. Lawrence says, offering a more lasting treatment solution for this cosmetic thorn.

"With the help of the new advances in fat processing, we hope that we will be able to fill these nonfacial areas, once we get grafts that can survive better in the target area," she says.

Many physicians are already performing fat grafting techniques in off-face locations, Dr. Lawrence says; however, the refinement of fat graft processing techniques could lead to an improved product and to more consistent outcomes, particularly in areas that are less vascular such as the redundant skin around the knees or other areas of aging redundant skin.

"The hope is that as we learn to process the fat better into smaller packets, maybe leaving some of the stem cells in the mix, maybe adding growth factors in the mix, we will get a fat transfer that lasts indefinitely. Though fat grafting won't necessarily surpass the popularity of synthetic fillers, the technique can be used in those patients that can benefit from it most, such as those with larger areas that need correction," Dr. Lawrence says. **DT**

Disclosure: Dr. Lawrence reports no relevant financial interests.

Better OPTIONS

Research helps to uncover new treatments for conditions in patients with skin of color

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — The common challenges in treating patients with skin of color have not changed over the years, but continuing research has borne new and innovative treatment approaches and techniques that can better and more safely address the conditions often seen in this patient population.

"Besides ochronosis, we haven't really seen any bad side effects with hydroquinone monotherapy."

Wendy Roberts, M.D.
Rancho Mirage, Calif.

"Patients with skin of color have always been more challenging to diagnose and treat because many cutaneous diseases and conditions can often present differently compared to the same 'textbook' diagnosis in Caucasian skin," says Wendy E. Roberts, M.D., a dermatologist in private practice in Rancho Mirage, Calif. "Being acutely aware of the varying presentations of a given condition across different skin types is crucial in not only exacting an accurate diagnosis but also in implementing an appropriate and safe therapy."

Skin of color is a combination of a diverse group of skin types, says Dr. Roberts, who spoke at the annual meeting of the American Academy of Dermatology. This includes African, Asian, Caucasian and Hispanic skin tones, as well as a growing population of mixtures thereof, all of which may respond differently to standardized procedures and treatments. Skin of color may often go unrecognized because the patient is mistaken for Caucasian alone. She says it behooves physicians to ask about ancestry and familiarize themselves with these varying skin types and the newest treatments that work best for a certain subset in order to maximize treatment outcomes.

Finding the best treatment

The variability seen among the different types of skin of color underscores the necessity of safer treatments in these patient populations, as different skin types will respond differently to a given treatment, Dr. Roberts says.

When performing therapeutic procedures such as surgery, chemical peels, cryotherapy and laser treatments, Dr. Roberts says it is paramount to keep skin of color in mind, as well as the type of skin color of the patient, as this vigilance will help guide the clinician's choice of therapy, which hopefully may lead to fewer complications.

"Complications from laser and light treatments are not uncommon in multicultural, global mixed racial skin types. Patients may not appear to have skin of color and wrong settings may be used, which can result in hyperpigmentation, hypopigmentation and scarring," she says.

Hypopigmentation and hyperpigmentation — such as vitiligo and melasma, respectively — are common conditions in patients with skin of color. Though truly effective therapies are few and far between, Dr. Roberts says, the first-line treatments for hypopigmentation and vitiligo are topical corticosteroids alone

BETTER OPTIONS see page 46

QUICK READ

A heightened vigilance regarding the patient's skin type, regardless of skin color, coupled with an in-depth knowledge of the latest and most effective therapies can help to maximize treatment outcomes and avoid complications.

It behooves physicians to **ask about ancestry** and familiarize themselves with these varying skin types and the newest treatments that work best.

Prepare their skin for greatness.

Introducing
NeoStrata®
SKIN ACTIVE
Perfecting Peel

Send your patients home with the tool for continuous skin perfection.

Enhance the benefits of your in-office peels, procedures and skin care recommendations with this safe (pH 3.7), convenient, advanced in-home treatment for visibly radiant, healthy-looking skin.

Improves the appearance of:

- Fine lines & wrinkles
- Uneven pigmentation
- Blemishes

From the creators of the original Glycolic Acid Peel

NeoStrata®
Elite Science. Professional Results.

For more information visit www.NeoStrataPro.com or call Customer Service 1-800-628-9904 (U.S. only)

Filler functions

Off-label indications grow, requiring derms to better understand each product and its particular nuances

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — Filler procedures have become a staple in the dermatologic armamentarium for the treatment of numerous cosmetic indications, allowing physicians to perform sophisticated soft tissue augmentation procedures in their patients, safely and effectively. Though the correction of nasolabial folds was the first and perhaps the most popular indication for fillers, nontraditional areas where these cosmetic tools can be implemented are ever growing.

"Most of the currently available dermal fillers have been FDA (U.S. Food and Drug Administration) approved for the correction of the nasolabial folds, because the nasolabial folds were one of the pioneering areas in cosmetic filler treatments and there is a very good rating scale gauging treatment success," says Rhoda S. Narins, M.D., clinical professor of dermatology, New York University School of Medicine, and director of the Dermatology Surgery and Laser Center, New York. "Though most of the fillers were initially approved for this indication, physicians are increasingly performing off-label aesthetic treatments, addressing a growing number of cosmetic indications."

> "Autologous fat is ... not the best choice for lip enhancement or fine-line filling."
>
> 
>
> **Rhoda Narins, M.D.**
> New York

> Autologous fat grafting can be useful for **correcting deformities and unevenness in body contour** after suboptimal liposuction procedures.

A number of nontraditional areas for soft tissue augmentation are being explored, include the earlobes, eyebrows, temples, tear trough, nose, lips, fine perioral lines, cheekbone area, chin, pre-jowl sulcus, jawline, hands, décolletage and nipples. Many dermal filler products and other filler techniques such as autologous fat grafting can be useful for correcting deformities and unevenness in body contour after suboptimal liposuction procedures, as well as for postsurgical repair, Dr. Narins says.

"I think the lips are now considered for many of the fillers as an area commonly treated, and some products have even recently received FDA approval for lip enhancement, bringing this indication into the mainstream of on-label filler treatments," Dr. Narins says.

QUICK READ

Dermal fillers are being used for numerous off-label indications, underscoring both the versatility of products, as well as the need for physicians to have an in-depth knowledge of the different options available.

Picking the right filler

The type of filler a clinician chooses will depend largely on the individual patient, how much the patient is willing to invest, and the critical decision made by the physician regarding which filler is best for a given area, she says. Depending on the anatomical location and cosmetic correction to be made, Dr. Narins says some filler products can be better than others.

FDA-approved filler products and techniques include those made of hyaluronic acid (HA), calcium hydroxylapatite, poly-L-lactic acid, polymethyl methacrylate, silicone (off-label as a filler), as well as autologous fat. Synthetic dermal fillers are based on various technologies and properties, and each product can be differentiated in part by their degree of cross-linking, concentration, gel hardness (or G prime) and cohesivity. According to Dr. Narins, choosing the right filler for the right indication is instrumental in achieving excellent aesthetic outcomes.

"In my experience, fat grafting can give you a lot of volume but it is not a very 'fine' filler. I believe that

FILLER FUNCTIONS see page 45

FILLER FUNCTIONS:

Soft tissue fillers get play in non-traditional areas from page 44

in addition to different synthetic fillers, autologous fat is an excellent option for volumizing the cheek area, correcting lipoatrophy or replenishing the lost volume under the eyes, but it is not the best choice for lip enhancement or fine-line filling," she says. "Furthermore, many patients do not have excess fat or do not want an additional surgical procedure to harvest the fat."

Patient selection for any cosmetic procedure is extremely important, and here, the physician has to critically evaluate and decide which filler would work best in a given patient based, in part, on several factors — such as the patient's skin and type of cosmetic issue, Dr. Narins says. Other factors that may play a role in choosing the appropriate filler include cost, the longevity of filler outcomes as well as a filler product that a patient feels comfortable with.

HA popularity

Hyaluronic filler products are very popular in aesthetic medicine not only because of the excellent treatment outcomes one can achieve, according to Dr. Narins, but also because these fillers can be very forgiving in that the results can be reversed with hyaluronidase after the procedure.

"In order to help avoid suboptimal treatment outcomes, I believe it is often best not to overcorrect the target area. Filler procedures can be performed in multiple sessions over time so that you never get an overdone look. Depending on the indication, I also often prefer to use cannulas as this may help reduce the risk of complications such as bruising," Dr. Narins says.

Physicians who perform soft tissue augmentation procedures should not only have an intimate knowledge of the local anatomy, but also should be well-versed in all of the available products and injection techniques, she says.

"Innovative dermal fillers have revolutionized the way physicians approach cosmetic augmentation procedures. As the off-label indications for these fillers continue to grow, physicians need to have a meticulous knowledge of each filler product and their fine nuances to be able to better decide which one works best for a given indication, ensuring maximum safety and aesthetic outcomes in their patients," Dr. Narins says. **DT**

Disclosure: Dr. Narins reports no relevant financial interests.

BETTER OPTIONS:

Treatments for patients with skin of color are evolving from page 42

and in combination with vitamin D3 analogues and calcineurin inhibitors. Second-line treatments that could be used in recalcitrant vitiligo lesions include narrowband UVB with calcineurin inhibitors, systemic corticosteroids, topical L-phenylalanine, topical antioxidants, as well as the excimer laser.

Bimatoprost for repigmentation

An interesting new treatment with topically applied bimatoprost ophthalmic solution (a prostaglandin analogue, PGF2alpha) has also shown some promising results in repigmentation, Dr. Roberts says.

In a small, prospective pilot study including 10 patients, Tarun Narang, M.D., of Gian Sagar Medical College, Banur, India, treated localized vitiligo lesions with bimatoprost 0.03 percent ophthalmic solution dosed at one drop per cm^2 twice daily for four months.

> The first-line treatments for hypopigmentation and vitiligo are **topical corticosteroids alone and in combination with vitamin D3** analogues and calcineurin inhibitors.

Results showed that seven out of 10 patients demonstrated pronounced repigmentation beginning on average after two months of treatment. At the four-month follow-up, three patients had a 100 percent repigmentation, three had 75-99 percent repigmentation, and 1 patient showed 50-75 percent repigmentation of the treated lesions.

Patients with recalcitrant stable focal vitiligo lesions on the face responded particularly well to the topical F2-alpha

analogue. Patients with disease duration of six months or less responded best to the treatment, with lesions on the face and scalp repigmenting the fastest, after only four to six weeks of treatment.

Although the mechanism of action remains unclear, Dr. Roberts says, it is thought to involve regulation of the melanocytes by prostaglandin. Dr. Narang recently presented the results of his study at the World Congress of Dermatology in Seoul, South Korea.

Gold standard

Hydroquinone remains the gold standard treatment for hyperpigmentation. Any emerging topical therapy in this field must show clinical efficacy equal or superior to hydroquinone in order to be considered a true alternative therapy, Dr. Roberts says.

Hydroquinone remains the **gold standard** for hyperpigmentation

"Besides ochronosis, we haven't really seen any bad side effects with hydroquinone monotherapy. Nevertheless, there has been a worldwide trend to get away from this bleaching agent and in its place, try new and emerging agents. This trend results mostly from manufacturing practices which result in hydroquinone tainted with mercury and other contaminants," she says.

Many different new proprietary products are showing to be very useful in the treatment of hyperpigmentation, Dr. Roberts says. Similar to hydroquinone, which targets one part of the melanin pathway by inhibiting tyrosinase, newer agents target multiple parts of the melanin pathway, including targeting the removal of stratum corneum pigment. Patients should also use sunblock with a SPF of 30 or higher, as UV radiation will contribute to a worsening of the condition. According to Dr. Roberts, the latest conventional wisdom is that the use of sunblock is extremely important in the treatment/prevention of melasma as well as for postinflammatory hyperpigmentation.

"This is a dynamic area with a lot of research yielding new and exciting products and techniques. Keeping up with the new literature and technologies are really the keys to success," Dr. Roberts says. **DT**

Disclosure: Dr. Roberts reports no relevant financial interests.

Dermatology Times

High-tech tools

Cutting-edge devices evaluate fine nuances of pigmented lesions

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — New and cutting edge technologies are proving useful for clinical diagnosis and early detection of melanoma. Depending on the diagnostic tool used, clinicians can improve their assessment of suspicious lesions and better evaluate the fine nuances differentiating benign and malignant pigmented lesions.

"The evolution of older as well as the development of new diagnostic tools used in the evaluation of suspicious pigmented lesions has significantly helped us in our efforts for secondary prevention of melanoma," says Harold S. Rabinovitz, M.D., a dermatologist in private practice and volunteer clinical professor, department of dermatology, University of Miami, Coral Gables, Fla. "These diagnostic modalities are proving to help in the clinical differentiation of different pigmented lesions, allowing us to more quickly arrive at a correct and timely diagnosis."

QUICK READ

New and evolving technologies can be very useful in helping clinicians differentiate and accurately diagnose suspicious cutaneous pigmented lesions. Here, a review of the latest and most relevant diagnostic technologies used for detecting skin cancer.

Closer look with dermoscopy

Dermatoscopes remain one of the cornerstone diagnostic tools for the evaluation of suspicious lesions. With the naked eye, dermatologists can reach a diagnostic accuracy for melanoma of about 60 percent, and with dermoscopy, that accuracy can be increased to about 80 percent, Dr. Rabinovitz says. Different structures in pigmented lesions can be better evaluated depending on the type of dermatoscope used.

Traditional or contact nonpolarized dermatoscopes can more optimally visualize epidermal features such as ridges, milia-like cysts and comedo-like openings characteristic of seborrheic keratosis, as well as regression structures (gray dots/granules) and the blue-white veil often seen in melanoma. But, Dr. Rabinovitz says, newer polarized light dermatoscopes can better visualize other features of melanoma, such as crystalline structures (altered collagen), polymorphous vessels and red areas (secondary to vascular changes).

According to Dr. Rabinovitz, hybrid dermatoscopes are now available on the market and allow you to view all of these different yet summarily critical features from one single device. Depending on the make, these units allow you to use either contact nonpolarized or polarized light mode by simply pressing a button on the side of the device or by simple clip-on attachments.

"Hybrid devices are very practical and useful in the evaluation of all features present in the lesion. Moreover, toggling between polarized and nonpolarized dermoscopy can help in highlighting specific structures because of the difference in the depth of imaging," Dr. Rabinovitz says.

HIGH-TECH TOOLS see page 52

Quotable

"Physicians should … encourage patients to be more compliant with using enough sunscreen consistently, as well as a higher SPF product."

Allan C. Halpern, M.D.
New York

on melanoma prevention
See story, page 54

Ipilimumab benefits may differ for patients with advanced mucosal melanoma

DT Extra

Patients with advanced mucosal melanoma typically show minimal overall response rate to ipilimumab, a recent study shows. At 12 weeks, researchers looked at radiographic tumor response, overall survival and toxicity in 33 patients who were given single-agent ipilimumab treatment. For the 30 patients who were assessable, radiographic measurement at 12 weeks showed one complete response (CR), one partial response (PR), and six stable disease cases. Overall response rate was 6.7%.

Source: *The Oncologist*

INTRODUCING

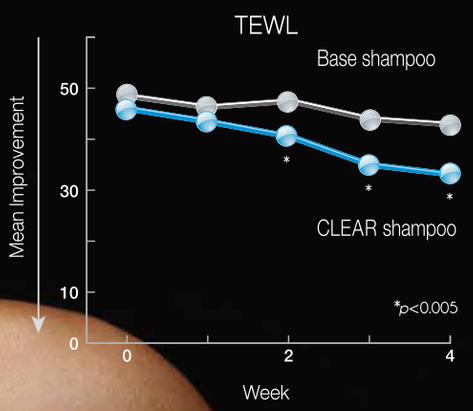
DANDRUFF SYMPTOM RELIEF
NOW WITH BARRIER REPLENISHMENT

NEW CLEAR COMPLETE CARE ANTI-DANDRUFF SHAMPOO

The scalp skin barrier of dandruff sufferers is compromised and in need of deep replenishment and repair. CLEAR is the first anti-dandruff shampoo to combine zinc pyrithione with Nutrium 10—a proprietary blend of barrier-replenishing ingredients infused with the deeply penetrating skin-identical lipid stearic acid.

The result? Dandruff symptom relief plus proven scalp barrier replenishment. And, its cosmetically elegant formula leaves hair strong and beautiful, so patients will love using it.

PROVEN CLEAR EFFECT ON THE SCALP BARRIER



Randomized, double-blind, half-head study (N=146). CLEAR was proven significantly superior at weeks 2-4.

CUSTOMIZED SOLUTIONS AVAILABLE FOR WOMEN AND MEN.

new CLEAR
SCALP & HAIR BEAUTY THERAPY™

Excision decision

Wide excision eliminates need for bone resection in subungual melanoma

Louise Gagnon
Staff Correspondent

Banff, Alberta — Subungual melanoma can be managed without amputating the distal digit, says an expert who spoke at the 7th annual Canadian Melanoma Conference.

The European experience and some experience at centers in the United States reveals subungual melanoma (which represents about 0.7 to 3.5 percent of melanoma subtypes) can be managed with en bloc resection of the nail instead of partial amputation, says Thomas G. Salopek, M.D., F.R.C.P.C., professor in the division of dermatology and cutaneous sciences, University of Alberta, and director of the Melanoma Clinic, University of Alberta, Edmonton.

More specifically, wide excision of the entire nail unit can be performed, with a safety margin of 5 mm to 10 mm, without the need for bone resection. A full-thickness skin graft is taken from the arm. No recurrences have occurred with this technique in seven cases with a mean follow-up time of 45 months (Sureda N, Phan A, Poulalhon N, et al. *Br J Dermatol.* 2011;165(4):852-858).

"It preserves function," Dr. Salopek says, noting preservation of function would be significant for some professionals like musicians.

Despite the absence of randomized, controlled trials to validate the appropriate management of subungual melanoma, standard treatment in North America has been partial amputation of the digit, explains Dr. Salopek, adding that an additional 62 cases in the medical literature demonstrate nonamputative management of subungual melanoma is safe and functionally superior to amputation.

Centers in Europe and some in the United States are currently offering nonamputative, conservative management of *in situ* or invasive subungual melanoma less than 1 mm in thickness.

In addition to function, patients and physicians have found the alternative approach to partial amputation produces a superior cosmetic result because most of the finger is left intact. Dr. Salopek emphasizes, however,

the approach is designed for thin melanomas, those that are less than 1 mm, and is not meant for melanomas that are very deep.

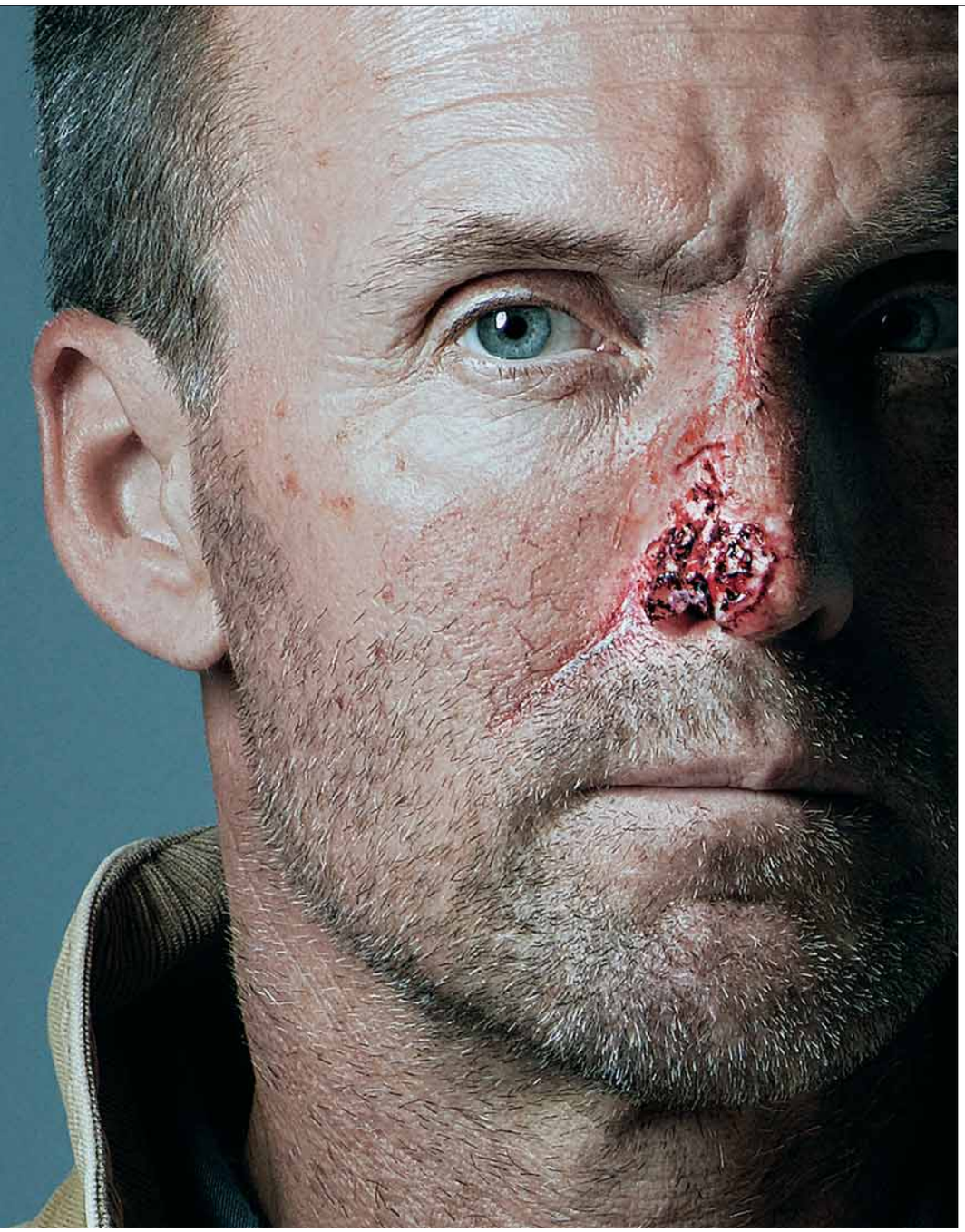
"If we find the tumor is more aggressive on wide excision then we go back to the basic (management) principles," Dr. Salopek says. He notes the approach is a suggestion for clinicians, not an official guideline.

Dr. Salopek also discussed the ideal management of lentigo maligna, an area that is controversial. Lentigo maligna typically affects skin that is actinically damaged, he says. Despite generous wide local excision, atypical melanocytes are often noted near the surgical margins. Re-excision specimens show similar results.

The current recommendation is wide-local excision, with a 5 mm margin, but this practice is not evidence-based, Dr. Salopek suggests. Indeed, the practice is based on a consensus panel from the 1990s.

"There is no scientific basis for this," Dr. Salopek says. "It is entirely based on opinion. There are no trials to validate or confirm the appropriateness of 5 mm margins."

EXCISION DECISION: see page 52



EXCISION DECISION:

Wide excision in subungual melanoma spares distal digit from page 51

The results of a retrospective investigation of 1,072 patients found that standard surgical excision of melanoma *in situ* with 9 mm margins of normal-appearing skin would result in the complete removal of 99 percent of melanomas *in situ*. In contrast, excision with 6 mm margins would clear only 86 percent of melanomas *in situ* (Kunishige JH, Brodland DG, Zitelli JA. *J Am Acad Dermatol*. 2012;66(3):438-444).

An alternative approach to managing lentigo maligna *in situ* is called staged margin-controlled excision, which is also known as the "spaghetti technique." This technique allows for 100 percent margin assessment.

The technique is reserved primarily for the face, a site where the cosmetic result is more of a priority to patients than sites on the body, Dr. Salopek says.

"You want to make sure you get all of the tumor, but you don't want to be excessive," he says. "You don't want to be removing too much tissue. In contrast, if it is on the trunk, you don't need to worry about a few millimeters."

Although Mohs' micrographic surgery is a reasonable alternative for treating lentigo maligna, with recurrence rates being quite low, many surgeons who perform Mohs' surgery are not comfortable performing this surgery for melanoma (Temple C, Arlette JP. *J Surg Oncol*. 2006;94(4):287-292). **DT**

Disclosure: Dr. Salopek reports no relevant financial interests.

HIGH-TECH TOOLS:

New devices dig deeper in ability to diagnose suspect lesions from page 48

RCM enables 'virtual pathology'

This noninvasive imaging technique allows for the en-face (horizontal plane) visualization of microscopic structures and cellular detail of the epidermis, dermoepidermal junction, and superficial dermis. Reflectance-mode confocal microscopy (RCM) can produce cellular resolution optically sectioned images of tissue, making the images very similar to those seen in sectioned histopathology of specimens, enabling a "virtual pathology" of the viewed lesions, according to Dr. Rabinovitz.

"Reflectance-mode confocal microscopy offers noninvasive high-resolution imaging of the skin, enabling the reconstruction of three-dimensional structures from the obtained images. These images can be extremely useful in the diagnostic work-up of suspicious lesions and can contribute to the decision-making process regarding the management of suspect lesions," Dr. Rabinovitz says.

The principle of RCM is similar to ultrasound, but instead of ultrasound waves, the system is based on the optical reflectivity, he says. In the technique, a point light source is used to illuminate a small spot within the tissue; the light is then reflected from the tissue and conducted through a small pinhole onto a detector.

"RCM is not only helpful in the evaluation of cutaneous lesions such as melanoma, but also with non-melanoma skin cancers and their differential diagnoses, ultimately assisting physicians in reaching an accurate diagnosis, which can lead to a quick and appropriate therapy," Dr. Rabinovitz says.

Multispectral imaging device

A multispectral imaging device can assist the clinician in the early detection and diagnosis of melanoma. This novel hand-held imaging device emits multiple wavelengths of light to capture images of suspicious pigmented skin lesions and extract critical data. The data are then analyzed against proprietary databases of melanomas and benign lesions using sophisticated algorithms in order to produce a recommendation of whether the lesion should be biopsied.

"The real novelty of this technology lies in its ability to see below the skin. While physicians can only see the top surface, multispectral imaging devices see below the skin up to 3.5 mm deep by virtue of multispectral imaging ranging from blue to infrared," Dr. Rabinovitz says.

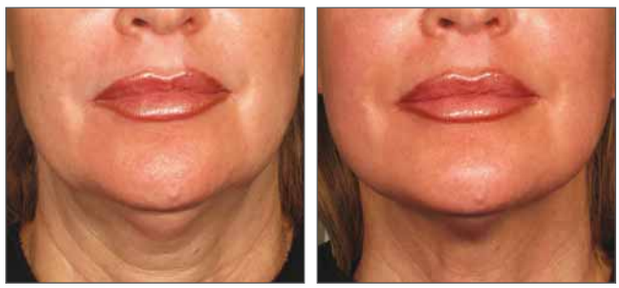
Multispectral imaging devices are only intended for lesions that are pigmented, clinically atypical, and between 2 mm and 22 mm in diameter. According to Dr. Rabinovitz, the added value of this multispectral imaging device — which is approved by the U.S. Food and Drug Administration — is that their technology is highly tuned to be sensitive to melanoma, and according to the FDA trial study (Monheit G, Cognetta AB, Ferris L, et al. *Arch Dermatol*. 2011;147(2):188-194), had a higher specificity than the average clinician assessment. This specificity was 9.9 percent for the device compared to 3.7 percent for the participating physician.

"Along with a careful clinical evaluation, these new and evolving technologies can significantly help us in more accurately and timely diagnosing suspicious lesions, and are welcome in our growing armamentarium of diagnostic tools," Dr. Rabinovitz says. **DT**

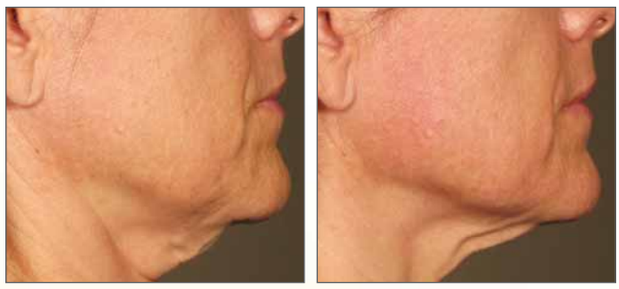
Disclosure: Dr. Rabinovitz reports no relevant financial interests.

HARNESS THE POWER OF SOUND TO TRANSFORM THE NECK AND FACE

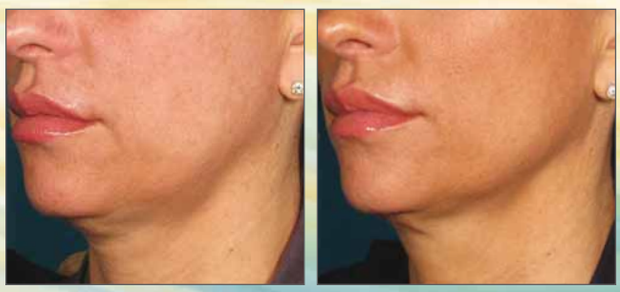
Ultherapy is the **ONLY** FDA-approved non-invasive lift of the neck and face



PRE-TREATMENT | DAY 90, *Single Treatment*



PRE-TREATMENT | DAY 180, *Single Treatment*



PRE-TREATMENT | DAY 360, *Single Treatment*

WHY CHOOSE ULTHERAPY?

- Supported by rigorous science and clinical evidence
- Treats deeper than Lasers and RF to lift the skin's support structure
- A single 60-90 minute procedure with NO downtime
- Noticeable results that last 1 year or more
- One of the best ROIs in the aesthetics industry

Visit **dt.ultherapy.com** to schedule a free educational meeting.

Ultherapy®

SEE THE BEAUTY OF SOUND™

For full product and safety information, including possible, mild side effects, visit Ultherapy.com/IFU.

OUNCE OF prevention

New measures, initiatives boost fight against skin cancer

By Ilya Petrou, M.D.
Senior Staff Correspondent

Barcelona, Spain — Initiatives addressing skin cancer prevention are always in flux, and while dermatologists support and promote secondary prevention methods including early and frequent skin cancer screenings, one expert says that still more can be achieved in primary skin cancer prevention.

"There is still need for improvement, including the mechanisms of educating the public in sun protection, the current state of sunscreen regulation and use, and the current state of tanning bed regulation and use," says Allan C. Halpern, M.D., chief of the dermatology service at Memorial Sloan-Kettering Cancer Center, New York, who spoke at the sixth World Meeting of Interdisciplinary Melanoma in Barcelona.

More than 10 years ago, a coalition known as the National Council for Skin Cancer Prevention (NCSCP) was founded with the central purpose of increasingly aligning messages and building on opportunities for public awareness regarding skin cancer and its prevention. In line with its common goals, the NCSCP has tried to raise awareness of melanoma and other types of skin cancer and instituted "Don't Fry Day" (the Friday before Memorial Day), similar to the American Academy of Dermatology's "Melanoma Monday" initiative (the first Monday in May).

"The hope is to raise public awareness of melanoma and teach the public effective strategies for melanoma prevention," Dr. Halpern says. "Fortunately, through the coordination of the efforts of many organizations, public health messages for melanoma awareness have become more effective and increasingly consistent."

QUICK READ

New measures and strategies including tighter restrictions on tanning beds and improved sunscreen labeling are setting the tone of melanoma prevention.

Advances in sunscreens

In sunscreens available today, SPF is mainly a UVB measurement. Nearly all sunscreens claim UVA protection or broad-spectrum coverage, but the degree of UVA protection is unknown, and most sunscreens offer incomplete — if not inadequate — UVA protection.

Industry is in the process of initiating compliance with the Food and Drug Administration's rules regarding labeling and testing for sunscreen products. The FDA has devised a standard for sunscreen labeling as relates to UVA protection, Dr. Halpern says, and it has adopted an *in vitro* pass/fail test (critical wavelength test) for broad-spectrum sunscreens in order to help ensure that products have adequate UVA protection.

According to the June 2011 FDA ruling, any sunscreen with an SPF of over 15 and a critical wavelength of over 370 nm may claim "if used as directed with other sun protection measures, sunscreens decrease the risk of skin cancer and early skin aging caused by the sun." Sunscreens that meet these two criteria can also include "broad-spectrum" as well as the appropriate SPF on the packaging.

"Even though there is only one study that indicates the efficacy of sunscreen in reducing the incidence of melanoma, the data is significant and cannot be ignored," Dr. Halpern says. (Green AC, Williams GM, Logan V, Strutton GM. *J Clin Oncol*. 2011;29(3):257-263). "Physicians should help patients better understand the new labeling of sunscreens and encourage patients to be more compliant with using enough sunscreen consistently, as well as a higher SPF product."

Tanning bed controversy

Some of the reasons to support the regulation of the tanning industry and tanning bed use are that tanning beds have very little supervision and guidelines, the UV radiation levels far exceed what is found in natural sunlight, and the side effects of their use are not monitored or regulated.

Measures to restrict the use of tanning beds, particularly in minors (i.e. younger than age 18) have increasingly been adopted by several countries worldwide, a motion that is widely viewed as a wise step toward skin cancer prevention. Despite tanning beds' increasing association with skin cancer, Dr. Halpern says the United States is still lagging behind in instituting legislation on the restriction of the devices.

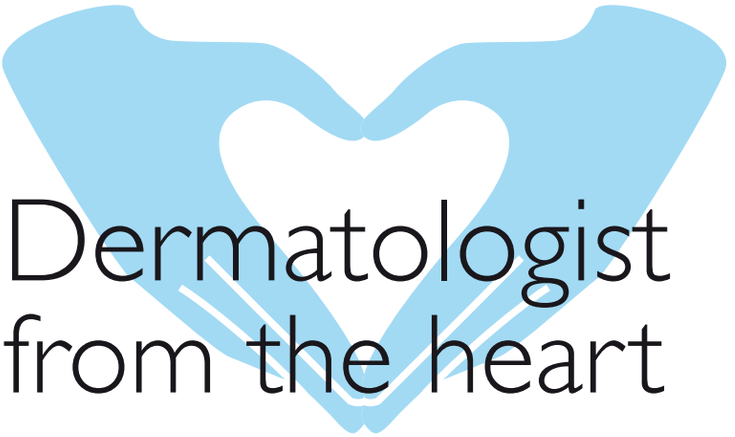
Although 32 states have enacted tanning bed legislation and have imposed some form of restriction on tanning facilities access to minors, Dr. Halpern says the restrictions themselves vary considerably and their enforcement is not uniform, underscoring the need to do more.

Physician counseling can play a role in addressing the use and abuse of tanning beds, and according to Dr. Halpern, dermatologists are a critical component of the advocacy, both on state and the federal levels, to achieve restricted use of tanning beds and a ban on their use by minors.

"It is a very exciting era in both the primary and secondary prevention of melanoma, and with recent clinical trial data indicating that sunscreens can dramatically decrease melanoma incidence, the labeling of sunscreens and their regulation becomes ever more important," Dr. Halpern says. "In addition, as we increasingly realize how big a problem tanning beds are in terms of contributing to melanoma risk, strict regulations on their use must also be instated."

Disclosure: Dr. Halpern reports no relevant financial interests.

CALLING ALL GRANT PROPOSALS!



Dermatologist from the heart

La Roche-Posay introduces a ground breaking initiative to make dermatology available to all!

The program will provide grants to fund community-oriented projects that support outreach designed to enhance the quality of life for patients.

Projects should fall under one of the following five categories:

- Information and Prevention
- Health Professional Training
- Advice and Support
- Improving Social Integration
- Improving Access to Healthcare

THE WINNER WILL RECEIVE **$10,000!**

Applications are **due by September 1, 2013.**
Winners will be announced in October.

Interested applicants must **submit grant proposals to:**
Secretariat General
La Roche-Posay Laboratoire Dermatologique
575 5th Avenue, 20th Floor
New York, NY 10017

Go to www.laroche-posay.us/dermfromtheheart for more details

LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

Dermatology Times

ASSET protection

Have you examined how your practice would fare if it were faced with baseless lawsuits or overzealous creditors?

By Brian Luster and Steven Abernathy
Staff Correspondents

QUICK READ

A limited liability company can insulate your assets from financial risks, as well as offer tax benefits.

One would be hard-pressed to find a better entity for asset protection than a limited liability company (LLC). It can effectively insulate you and your practice from certain financial risks and offer tax benefits.

First introduced in Wyoming in 1978, LLCs have been adopted by all 50 states. They were promulgated to solve some of the problems inherent in both corporate and partnership structures. For instance, the tax treatment of LLCs, like partnerships, is pass-through, resulting in only one layer of tax. Unlike partnerships, however, which require at least two parties, LLCs can be formed with only one member (and the pass-through tax treatment preserved by electing to treat it as a "disregarded entity" for income tax purposes). And they do not require the maintenance of rules and formalities of corporations.

Consider setting up multiple LLCs for ultimate protection. Certain states (for instance, Texas and Illinois) allow the use of the series LLC, the purpose of which is to streamline the ability to separate assets into their own entities, minimize liability, and reduce paperwork and formation costs. Such structures involve a "father" LLC and several "children" LLCs, each sub-LLC with its own books and members.

LLCs are relatively easy-to-understand asset protection firewalls. Ask yourself whether you are better off investing a small amount to protect valuables you have worked your entire life to earn. If the answer is yes, then think of an LLC as a driver in your golf bag—not the only club in your asset protection bag, but certainly not a bad tool with which to tee off.

No better method exists to protect your savings from creditors than by ensuring that they remain untouchable through impermeable trusts and proper estate planning. That element is the essence of asset protection.

Learning the hard way

One of our successful physician colleagues, whom we will call Dr. Stevens, learned that lesson the hard way. He owned multiple assets, including a speedboat, a vacation home, an apartment building, a brokerage account, and a plot of undeveloped land. One day, his son and a group of his friends took a joyride in Dr. Stevens' speedboat. His son ended up hitting a dock at full speed, crippling his two friends. Alcohol was involved, and Dr. Stevens was slapped with a multi-million dollar lawsuit, far in excess of the speedboat's policy limits.

Dr. Stevens believed he was

ASSET PROTECTION see page 60

Quotable

Although most physicians were never trained on how to become effective leaders, it is an art and skill that can be learned.

Robert Taylor, M.D.
Portland, Ore.

on how to be a better leader

See story, page 60

Research demonstrates need for safety initiatives

DT Extra

Dermatology practices could benefit from establishing safety initiatives in several key patient care areas, a survey finds. Researchers collected and categorized information on recent and most serious physician-reported errors. Of 153 responses, the researchers noted that the most common categories of recent and most serious errors related to assessment and interventions. Assessment errors often involved the biopsy pathway, the researchers noted; while most recent and most serious intervention errors were related to medication and procedures.

Source: *Journal of the American Academy of Dermatology*

Dermatology Times®

News and Analysis for Today's Skincare Specialists

Now dermatologists can access practical clinical, regulatory and business information anywhere, anytime.

Introducing the Dermatology Times app for

iPad and iTunes

Download it for free today at

www.DermatologyTimes.com/DermatologyTimesApp


Joel M. Blau, C.F.P., left , is president and **Ronald J. Paprocki, J.D., C.F.P., C.H.B.C.,** is chief executive officer of MEDIQUS Asset Advisors Inc. in Chicago. They can be reached at 800-883-8555 or blau@mediqus.com or paprocki@mediqus.com

IRAS: KNOW THE RULES ON TAKING DISTRIBUTIONS

Failure to withdraw required amounts after retirement can result in a harsh IRS penalty

Q What are the rules associated with retirees taking money out of their retirement plan or IRA?

a: We are often so focused on the benefits of contributing to a retirement plan or individual retirement account (IRA) that we forget about eventually having to address the distribution phase. What many retirees often don't realize is that the Internal Revenue Service (IRS) not only limits the amount you can contribute to qualified retirement plans and IRAs while you are working, but it also tells how much you must withdraw when you're retired. Under the rules for "required minimum distributions" (RMDs), you may have to take distributions before the end of the year.

First, know that distributions from qualified retirement plans and IRAs are taxed at ordinary income rates, reaching as high as 39.6 percent in 2013. In addition, you must pay a 10 percent penalty tax on distributions received prior to age 59½ years, unless a special exception applies (Internal Revenue Code section 72[t]). On the other hand, RMDs are not required for Roth IRAs.

Usually, you must begin taking RMDs no later than April 1 of the year following the year in which you reach age 70½ years. For example, if you are turning age 70½ this year, the first distribution must occur by April 1, 2014. But if you wait that long, then you will also have to take another distribution for the 2014 tax year by Dec. 31, 2014. To avoid the doubling up of payouts in 1 year, you must arrange to take your payout prior to April 1 of the year after you are turning age 70½. Once you pass 70½, you must continue annual distributions each year.

However, there is an exception to these rules if you still work on a full-time basis and you do not own 5 percent or more of your practice or other business entity. In this case, you are allowed to postpone RMDs until your actual retirement.

How much do you have to withdraw? The amount of the annual RMD is based on the IRS life expectancy tables for the participant and the value of the account on the last day of the previous calendar year. In other words, your RMD for the 2013 tax year depends on your balance as of Dec. 31, 2012, even though you're taking out the funds almost a full year later. Your financial adviser or tax adviser can help you determine the amount of your specific required distributions. In addition, there are many websites that have RMD calculators so that you can do it on your own, if that is your preference.

If you fail to comply, the IRS may impose a harsh penalty equal to 50 percent of the amount that should have been withdrawn, or the difference between the required amount and a lesser amount actually withdrawn. The penalty is added to the regular income tax that is due on the RMD. To avoid any potential problems, be sure to take your distributions well in advance of the Dec. 31 deadline.

The key is to be proactive and plan accordingly. Keep in mind that during your retirement years, you will have two separate pools of assets to draw from: qualified (retirement plans and IRAs) and non-qualified (personal investment portfolios). By utilizing distributions from both sources, you can create a retirement income stream that minimizes income taxation, avoids penalties, and maximizes the efficiencies within your overall coordinated financial plan.

Q Does it make sense to invest in international real estate investment trusts?

a: Real estate investment trusts (REITs) were introduced in the United States back in 1960. From an international standpoint, the success and growth of the U.S. REIT industry prompted a number of cities and countries throughout Europe and Asia to introduce legislation allowing for the adoption of REIT-like structures. One of the greatest benefits of including international real estate in a portfolio is its low correlation with other major asset classes, such as small- and large-cap U.S. stocks and domestic bonds. It is important to keep in mind that, just like with domestic and international stocks and bonds, investing in publicly traded REITs, whether through direct ownership or a mutual fund, carries certain market risks, including the general level of real estate values, REIT dividend payouts, management skill, and broad stock market trends. **DT**

Bio-Oil® is a skincare oil that helps improve the appearance of scars, stretch marks and uneven skin tone. It contains natural oils, vitamins and the breakthrough ingredient PurCellin Oil™. For comprehensive product information and results of clinical trials, please visit bio-oil.com. Bio-Oil is the No.1 selling scar and stretch mark product in 11 countries. $11.99 (2fl.oz.).

10 WAYS TO BE A BETTER LEADER

Leadership is the art of engaging the hearts and minds of others to help them shape the future, says Robert Taylor, M.D., professor emeritus of the Department of Family Medicine, Oregon Health and Science University's School of Medicine.

And their future is shaped by those who believe in the vision of the leader. Dr. Taylor says leadership is the opposite of reading a book. You plan the ending first, then do everything you can to get there.

Although most physicians were never trained on how to become effective leaders, Dr. Taylor says it is an art and skill that can be learned.

He outlined 10 ways to physicians can cultivate their leadership skills:

1 **Define a vision.** Good leaders not only have a compelling vision, they "will not rest until that vision becomes a reality," he says.

2 **Share this vision.** "Leadership is not passive, it is an active activity," Dr. Taylor says. "Persuade others to join the quest."

3 **Recognize your style.** There are six leadership styles, including autocratic, dictatorial, facilitative, bureaucratic, parental, and charismatic. Which style are you?

4 **Differentiate between leadership and management.** Leaders have a vision, and managers carry out the vision. Leaders do the right thing; managers do things right. Both are important concepts, he says; but they are clearly different.

5 **Learn and play by the rules.** Although you don't have to think by the rules, Dr. Taylor calls them "the scar tissue of past errors." It is very important to learn from past mistakes.

6 **Earn the trust of those you lead.** Make rational, mission-based decisions, reconcile your vision with your values, and guard your credibility, Dr. Taylor says.

7 **Recognize the power of leadership.** "Margaret Thatcher said, 'Being in power is like being a lady. If you have to tell them you are, you aren't.'" Use power sparingly, and share power appropriately and progressively, Dr. Taylor says.

8 **Act like a leader.** If you are chosen to lead, then play the part. Leaders not only model the behavior, they set the example.

9 **Turn followers into leaders.** Empowering your staff to make decisions is an excellent leadership trait, Dr. Taylor says. And when you see staff making a sound decision, acknowledge it.

10 **Maintain balance in your life.** Turn work into play, and play hard.

"Good leaders effect change," Dr. Taylor says. "The best leaders leave behind the will to pursue the dream."

Medicine is in a time of great transition, Dr. Taylor says. Sound leadership will be more important for practices to thrive in a competitive and rapidly changing healthcare environment over the next few years. **DT**

ASSET PROTECTION

Know how to fare against lawsuits and creditors from page 56

adequately protected. Years earlier, a patent lawyer had advised him to put his brokerage account, vacation home, and land in a corporation. Doing so, the attorney had said, would insulate him from liability because of the limited liability benefits of a corporation.

That was poor advice. Although a corporation provides a level of protection from liability, this protection typically only applies to negligent actions of the corporation itself. And because the damage was the result of the speedboat accident (and the boat was not owned by the corporation), nothing was stopping the plaintiffs from simply seizing the stock and then dissolving the company. In addition, the corporation was subject to double taxation at both the corporate and shareholder level, meaning that his brokerage account gains were taxed twice.

Dr. Stevens, unsurprisingly, failed to keep up with a bevy of required corporate formalities.

He would have been better served by including the speedboat and remaining assets in an LLC—preferably separate LLCs. If Dr. Stevens' brokerage account and land had been in separate LLCs, the plaintiffs would have had a difficult time directly seizing them.

Outside, inside liability

This is an example of outside liability, or, liability not related to the property. Because nothing exists for the litigants to go after, the rest of his assets are protected. In such a case, the litigants most likely will accept the insurance company's policy limit.

Inside liability involves liability stemming from the property itself. Suppose a tenant slipped on the sidewalk of one of Dr. Stevens' rental properties. If this property is in an LLC, then he is safe from claims stemming from the injury.

At the heart of the LLC asset protection is the ability to increase one's bargaining power. Because Dr. Stevens' assets are protected, his pockets are suddenly much shallower, making him a far less tantalizing target for personal injury attorneys. He is now in a better position to settle the case for a fraction of what he is being sued.

Note, however, that recent case law has revealed chinks in the LLC armor. California and Florida have both ruled that, although a creditor cannot seize assets in the LLC, it can foreclose on the member interest on the LLC. Before these rulings, a creditor's only remedy was to obtain a charging order, which essentially allows the creditor to obtain any distributions. This remedy largely was toothless, however, because it could not force distributions. Be sure to consult your professional advisers to determine the appropriate business arrangement for your practice and ensure that it is set up properly so you can maximize the benefits. **DT**

The authors are physicians' advocates and founders of the first Physician Family Office (PFO) in the country. The PFO sells no products, receives no commissions, and is independent, employee-owned, and governed by an advisory board.

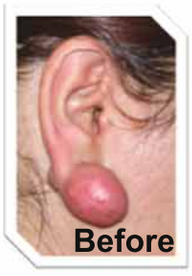
Sensus Healthcare

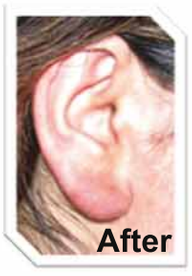
Taking New Aim at Skin Cancer™

Superficial Radiotherapy

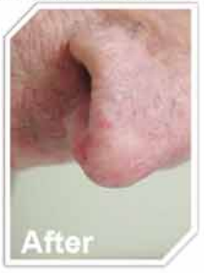
Now FDA-Cleared To Treat . . . *Keloids*

Earlobe Keloid

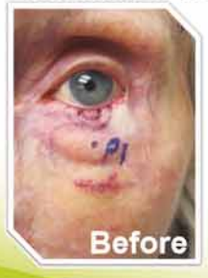


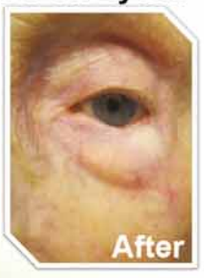


1cm x 1cm BCC on Nose



0.3cm x 0.4cm BCC on Eyelid





SRT-100™

Contact Us For More Information

Toll Free: 800-922-5808

Web: www.sensushealthcare.com

e-mail: info@sensushealthcare.com

Lyle Melick is IT manager for SS&G Healthcare Services in Akron, Ohio.

EXAMINE all costs

Know the differences and what you're getting when assessing EHR platforms

Nearly 75 percent of U.S. medical practices are using electronic health record (EHR) systems, and because of federal mandates, such as meaningful use, the number is expected to grow.

If you are purchasing an EHR system for the first time or considering switching systems, you need to first assess the needs of the practice and then consider the different system platforms (cloud- or software as a service [SAAS]-, or server-based). With a server-based system, all the hardware and software, as well as the records themselves, are kept on-site. With a cloud-based system, patients' records are stored in a remote location hosted by the vendor, and doctors and their staffs access them via the Internet.

Server-based systems require you to purchase and service the equipment on which patient records are stored, but they provide the peace of mind of knowing that your patients' records are in your office and at less risk of being stolen while being sent to a remote server via the Internet.

Here is a more detailed look at the main elements of each type of system.

Server-based systems

If you choose a server-based system, you next need to consider the size of your server. Your EHR vendor will make a recommendation, but most small practices can function with a 200 to 300 gigabyte hard drive, which is enough to store records for about 10,000 patients. A server of this size will cost between $5,000 and $8,000, and you can expect it to last about five years.

Next you will need to decide whether to access the server via desktop computers or wireless devices. If you use desktops, I recommend purchasing "business class" machines. These will cost between about $800 and $1,000 per computer but last longer than computers purchased for home use.

Linking computers to the server and each other usually will cost roughly $150 and $200 per "run" (link). Specify the use of wiring that is at least category 5 to ensure that your data are transmitted quickly and reliably.

If you decide to use wireless devices for server access, you will need a Wi-Fi base station, which generally will cost $500 to $700. Check that wireless transmissions can work well in your building and that all your wireless devices have built-in Wi-Fi receivers.

QUICK READ

Before you approach an EHR vendor, assess the needs of the practice and then consider the benefits of different system platforms.

After you've installed your EHR, keeping it running efficiently is crucial. Most small practices contract with an outside information technology (IT) company to maintain their systems. These companies can monitor your system's functions remotely and will send someone to your office if on-site trouble-shooting is required. Contracts with IT service companies usually cost around $300 to $500 per month. Ask your EHR vendor or hospital IT department for a recommendation.

Cloud or SAAS?

Cloud- or SAAS-based systems require a far smaller initial investment than do server-based systems. Usually all you will need are devices for accessing the Internet (computers, smart phones, iPads, etc.), an Internet connection, and a router—in addition to the licensing fee for the EHR itself. The vendor will charge a subscription fee based on the number of providers in your practice.

A possible pitfall of cloud-based systems is that vendors sometimes are less than cooperative about transferring patients' data if you decide to change vendors. It is a good idea to include in your contract a deadline by which the vendor must transfer your patients' information if you switch vendors.

Take the time to research systems thoroughly, interview vendors, and ask colleagues how satisfied they are with their system. Doing the homework at the beginning will save you from costly mistakes later. DT

Palomar
FROM LIGHT COMES BEAUTY

The fastest laser hair removal system EVER!

With the largest spot size available and it's high-speed pulse rate, the Palomar Vectus Laser offers the fastest hair removal treatment available on the market today – allowing aesthetic practices to comfortably clear unwanted hair on even the largest body areas in just minutes.

In head-to-head competition, the Palomar Vectus Laser proved to be over two and a half times faster than competitive hair removal lasers*. Your clients will love the short treatment sessions, and your staff won't miss the tired arms and cramped hands. Faster really is better with the Palomar Vectus Laser.

*Don't just take our word for it; watch a head-to-head comparison and take "**The Vectus Challenge**" for yourself at **www.vectuschallenge.com***

*** Video on file**

Palomar Medical Technologies Inc. 15 Network Drive, Burlington, MA, 01803 USA | USA: 1-800-PALOMAR
USA: www.palomarmedical.com

HIPAA:

Your liability is increasing; this is what will constitute compliance

from page 1

HHS defines as "an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability" of electronic protected health information (PHI) in your practice;

- reviewing the practice's policies and procedures for when PHI is lost or stolen or otherwise improperly disclosed, and making sure your staff members are trained in them;
- ensuring that the electronic PHI your practice holds is encrypted so that it cannot be accessed if it is lost or stolen (see "Encrypting your patients' health information");
- modifying the practice's electronic health record (EHR) system so that you can flag information a patient does not want shared with an insurance company;
- having the ability to send patients their health information in an electronic format;
- reviewing your contracts with any vendors that have access to your practice's PHI; and
- updating your practice's notice of privacy practices.

OTHER PROVISIONS

Other provisions of the omnibus rule include restrictions on selling PHI or using it for marketing and fundraising purposes without obtaining the patient's permission and loosening some of the restrictions on sharing PHI with family members or other caregivers of deceased patients.

Disclosure is only permitted, however, to the extent that the PHI is relevant to the role the family member or caregiver played in the decedent's treatment. Moreover, release is not permitted in cases in which the individual expressly stated before death that he or she did not want the PHI released.

The omnibus rule also permits doctors in states with compulsory vaccination laws to disclose a child's immunization records to schools without obtaining formal authorization from parents. Physicians now can do so with only a verbal agreement, provided they document that they obtained the permission. Lastly, the rule prohibits health plans from using or disclosing genetic information for the purpose of insurance underwriting.

Hiring **a single vendor** ... can seem expensive, but doing so may be **more economical.**

The rule also sets and describes the four categories of penalties for violating the rules and the dollar amounts for each.

The omnibus rule is the latest step in a process that began when Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. Among other provisions, the HITECH Act required HHS to strengthen HIPAA's privacy and security protections for health information. HHS adopted interim rules for doing so in 2010 and finalized the rules with adoption of the omnibus rule.

GROWTH IN EHRS DRIVE CHANGES

Driving many of the changes in the omnibus rule is the privacy debate, especially as it relates to electronic health records, says Dr. Davey. "The original HIPAA went into effect in 1996. And that relates more to how we handle records," he says. "Now they're tightening it up in terms of who has access to data ... and that's the part that is aimed at the electronic records."

Angela Dinh Rose, director of health information management excellence for the American Health Information Management Association, says, "HITECH was a huge factor in pushing the adoption of health information technology, so along with that, Congress saw the need for improved privacy and security practices to protect patient information now that so much

HIPAA see page 66

HIPAA rule violation categories and penalty amounts

The Health Insurance Portability and Accountability Act omnibus rule establishes four "tiers" of violations, based on what it terms "increasing levels of culpability," with a range of fines for each tier.

VIOLATIONS of the same requirement or prohibition for any of the categories are limited to **$1.5 million** per calendar year.

The language of the rule states that actual dollar amounts will be based on "the nature and extent of the violation, the nature and extent of the resulting harm, and other factors … includ(ing) both the financial condition and size of the covered entity or business associate."

CATEGORY	FINE RANGE
Did not know of breach	$100 to $50,000
Had reasonable cause to know	$1,000 to $50,000
Willful neglect, corrected	$10,000 to $50,000
Willful neglect, not corrected	$50,000

MORE HIPAA GUIDANCE COMING

The website HealthITSecurity.com reported in late April that the Department of Health and Human Services (HHS) will issue additional Health Insurance Portability and Accountability Act (HIPAA) guidance. An HHS spokesperson wrote in an email to the website that "we will be issuing additional compliance guidance and technical assistance … that was not addressed in the preamble of the Omnibus Rule given space limitations. We hope to publish these materials … soon."

The additional guidance will appear on the website of the Office for Civil Rights (www.hhs.gov/ocr/office/index.html), which is responsible for enforcing HIPAA rules.

HIGH PROTECTION

Tinted Compact SPF 50

FRAGRANCE-FREE
PARABEN-FREE
WATER RESISTANT

RECOMMENDED
SKIN CANCER FOUNDATION
ACTIVE

EAU THERMALE
Avène

Protect your skin with 100% Mineral Sun Care

- Broad spectrum UVA/UVB SPF 50 sunscreen
- Powerful antioxidant protection
- Soft-to-touch texture with matte finish
- Safe for sensitive and post-procedure skin

HYPOALLERGENIC • NON-COMEDOGENIC

Laboratoires dermatologiques
Avène
PARIS

23RD WORLD CONGRESS OF DERMATOLOGY
VANCOUVER 2015

SILVER SPONSOR
Pierre Fabre

www.aveneusa.com

The Skin Cancer Foundation recommends
this product as an effective Broad Spectrum sunscreen

HIPAA:

Your liability is increasing; this is what will constitute compliance from page 64

of it is becoming electronic."

According to a study of breaches reported on the HHS website by Kaufman, Rossin & Co., an accounting and consulting firm based in Miami, the number of individuals affected by data breaches doubled from 2010 to 2011, even though the number of entities involved in a breach declined (see below, "Summary of health breach information reported to HHS, 2010 to 2011"). The largest cause of breaches was theft (53 percent), followed by unauthorized access (20 percent) and loss (14 percent).

NEW RULES FOR DATA BREACHES

The changes likely to have the greatest effect on dermatologists are those concerning how PHI should be secured and kept private and what practices must do in case of a breach — meaning the PHI is lost, stolen, or otherwise made available to someone who should not have it.

Why? Whereas before the omnibus rule, breaches only had to be reported if they involved a "significant risk of harm," now the presumption is that virtually any unauthorized disclosure of PHI may be a breach, unless the practice can demonstrate a low probability that the information has been compromised, explains Kenneth Rashbaum, J.D., a health law attorney with Rashbaum Associates in New York.

"These changes are a big deal because the standard (of what constitutes a reportable breach) is much lower, and as a result there's now a presumption of harm to the patient by virtue of the breach by the entity that made the disclosures," Mr. Rashbaum says.

Given the new standard, the most important action practices can take to protect themselves against penalties, experts emphasize, is to encrypt patient data, both within the practice itself and when they are taken outside the practice in a laptop computer, smartphone, or other portable device. Why?

"In the (omnibus) rule now, they're defining a breach as the loss of unsecured PHI," explains Juli A. Ochs, C.P.A., healthcare engagement director for the consulting and accounting firm CliftonLarsonAllen LLP. "So anything that renders the data 'unusable, unreadable, or undecipherable' is now not considered a breach." (See "Encrypting your patient's health information," page 68, for suggestions on how to encrypt data in a way that meets HHS requirements.)

DETERMINING RISK OF HARM

Whenever a breach does occur, it is presumed to be reportable to HHS unless the practice can demonstrate a low risk of probability that the PHI will be compromised, meaning that anyone will be harmed as a result. Demonstrating the risk contains four components:

- **The nature and extent of the data involved.** "Was the information just a list of patients? Did it include identifying data like Social Security numbers or other financial information? Were there intimate medical or psychotherapy records? Those are the types of questions that need to be asked," says Aldo Leiva, J.D., a data security and privacy attorney in Coral Gables, Fla.
- **The unauthorized person** who used the PHI or to whom it was

Summary of breach information reported to HHS, 2010 to 2011

Source: Kaufman, Rossin & Co.

TOTAL **357** BREACH REPORTS **16.2** MILLION AFFECTED INDIVIDUALS

The **most important action** you can take to protect your practice against penalties, experts emphasize, is to **encrypt patient data,** both within the practice and when they are taken outside the practice in a laptop computer, smartphone, or other portable device.

disclosed (something you can't know if the breach resulted from a device being lost or stolen).

➔ **Whether the PHI was actually acquired or viewed.**

➔ **The extent to which the risk has been mitigated after the fact.** An example, Mr. Leiva says, might be having a contractor to whom the PHI accidentally was sent sign a nondisclosure agreement.

In addition, the rule requires practices to notify patients whose PHI has been breached within 60 days of discovery of the breach. If the breach affects more than 500 patients, then HHS and the local news media must be notified within the same 60-day time frame. Practices must keep a log of all breaches regardless of the number of patients affected, and they must submit the log annually to HHS.

Another requirement of the rule is that practices and other covered entities conduct a risk analysis. The purpose of the exercise is to discover where the practice might be vulnerable to having its patient information lost or stolen — through theft of a laptop computer on which data are stored, for example — and putting in place policies and procedures to reduce those vulnerabilities.

"People get overwhelmed by this, because they think it needs to be a formal process," Ms. Ochs says, "but it can be just everyone in the practice sitting down to talk about where are we vulnerable, assessing the risk of each vulnerability, deciding how to address it, and then documenting that they've gone through the process."

In addition, practices should appoint a privacy and security officer with the responsibility for making sure the practice has policies and procedures for complying

HIPAA see page 68

HIPAA:

Your liability is increasing; this is what will constitute compliance from page 67

with the rules and that staff members are trained in them. Practices can — and often do — assign the responsibilities to a current employee rather than hire someone new, Ms. Ochs says. "The main thing is just that it's assigned," she adds.

Violators of the privacy and security rules will be fined in amounts ranging from $100 to $50,000 per violation (see "HIPAA rule violation categories and penalty amounts," page 64). The maximum a practice or other covered entity can be fined in a year is $1.5 million.

RELATIONS WITH BUSINESS ASSOCIATES

After changes to the PHI security and breach notification rules, the omnibus rule changes of greatest interest to practices are those affecting their relationships with "business associates," vendors that have access to a practice's PHI. Such vendors are now directly responsible to HHS for securing and guarding the privacy of PHI in the same way that practices are, and they are subject to the same penalties.

"Before (the omnibus rule), physicians and medical organizations might be protecting patient data the way they were supposed to, but their third-party providers were not obligated except under the terms of their contract with the providers," notes Jorge Rey, C.I.S.A., C.I.S.M., director of security and compliance for Kaufman, Rossin & Co. "Now the rules say that if you have access to patient healthcare-related information, you need to comply with all the privacy requirements." The rule also puts subcontractors to practice vendors under HHS jurisdiction.

The increased responsibility of business associates does not let dermatologists off the hook entirely. That's because even if the business associate loses PHI or has it stolen, the dermatology practice ultimately is responsible for notifying affected patients and reporting the breach to HHS.

Mr. Leiva notes that many health information technology (HIT) vendors and consultants include boilerplate language in their contracts absolving them from liability for data loss. Consequently, he advises reviewing all contracts with HIT vendors to ensure that their wording conforms with the omnibus rules governing relations between covered entities and their business associates. (A sample business associate agreement is available from the government at http://go.cms.gov/186eAZP)

GREATER PATIENT CONTROL

The third part of the omnibus rule affecting dermatologists' practices

Encrypting your patients' health information

ALTHOUGH ENCRYPTION has long been part of an effective data security strategy, the Health Insurance Portability and Accountability Act omnibus rule makes it more important than ever. That's because the requirements for reporting lost or stolen data that are unusable by anyone else are far less onerous than those for unencrypted data.

Mark Eich, a partner and director of information security for the accounting and consulting firm CliftonLarsonAllen LLP in Minneapolis, notes that numerous encryption tools are available through a Web search. He advises thinking about protected health information (PHI) in two forms: when it is "at rest" (stored) and when it is transmitted.

Start by cataloging where your PHI is at rest in the organization. "It could be servers, work stations, mobile devices, or all of them. That will tell you where you need to apply encryption tools," he says.

On his own laptop, Mr. Eich uses Windows Bitlocker Drive Encryption software, which encrypts everything on his main drive and requires entry of a user ID and password to access.

"If someone steals my computer, they'd need the encryption key to actually interact with the data," he says. Most encryption devices automatically encrypt data when they are transferred to another device, such as a flash drive or smartphone.

Encrypting data for transmission generally requires use of a secure file server and transfer tool so that the data can only be accessed by a password or other key provided to the recipient. Mr. Eich says his firm uses a server called LeapFile to transmit PHI. After files are uploaded to the server, he sends the client credentials and a link that applies only to those data.

Although PHI also can be transmitted via standard email, it is a far less secure method, and few security experts recommend it. In fact, many health systems and others dealing with PHI have blanket policies forbidding the use of email to transfer it. "That's a decision you need to make right from the start," Mr. Eich advises. DT

"If someone steals my computer, they'd need the encryption key to actually interact with the data."

Mark Eich
Partner and director of information security, CliftonLarsonAllen LLP

COMMENTS

"#HIPAA affects you, yes YOU. bit.ly/15F22HY #BHSinsurance"
@BHS_INS

"HHS seeks input and comments on #HIPAA audit process ow.ly/IFws8 #EHR #physicians #hospitals"
@HIGHTECHANSWERS

"When health data is stolen, lawsuits often follow ow.ly/IAUVC #EHR #HIPAA #ptsafety"
@SIGMUNDSOFTWARE

"Pritts: This isn't about nuances ... you don't have to check your common sense in order to comply with HIPAA omnibus #hdpalooza"
@ONC_HEALTHIT

"#HIPAA security challenges will be felt across industries through business associates - who will need to comply for healthcare and then more"
@KIRKJNAHRAWORK

"Is your practice's computers still running on Windows XP? In April 2014, your medical records will be a HIPAA risk ow.ly/IHL8Z"
@REBECCAMOREHEAD

Will you be ready for the expanded HIPAA provisions?
Comment today @ https://www.facebook.com/questions/62344404370899

To view current poll results and other responses, visit https://www.facebook.com/questions/623244404370899

concerns patients' rights related to their own health information. The rule gives patients the right to:

- obtain copies of their health information in an electronic format within 30 days of requesting it, with one 30-day extension permitted, and;
- instruct his or her doctor not to share information about a test or treatment for which the patient has paid out-of-pocket with his or her insurance company.

In addition, the rule requires practices to update their notice-of-privacy policies (NPPs) to reflect the changes to patients' rights included in the omnibus rule and requires sending the updated NPP to all patients and posting it prominently in the practice and on the practice's website.

MISALIGNED REGULATIONS

The idea behind EHRs was to have federal information exchanges that would allow hospital systems, outpatient facilities and individual physicians to exchange patient information, Dr. Davey says.

"We do not know when this will happen. In my part of the world hospital systems are rolling out a common electronic record to the primary care doctors, giving hospital staff members electronic access to records and setting up secure texting networks," Dr. Davey says.

Dermatologists should ask their EHR vendors about a timetable for implementing a function that allows them to meet the requirements by the Sept. 23 deadline, advises Lisa Gallagher, C.I.S.M., vice president of technology solutions for the Healthcare Information and Management Systems Society. If a vendor won't be ready to provide such a feature, then the practice will have to still find a way to meet the requirement, maybe through a different way of recording the patient's data until the function is available, Ms. Gallagher says.

"Sometimes regulatory requirements are misaligned," Ms. Gallagher adds. "What's happened here is the requirement for the provider to do something, and the requirement hasn't made its way down to the vendor. But the important thing for everyone to realize is that HHS has said this requirement is going into effect and you have to meet it." **DT**

BTL AESTHETICS

Device improves skin laxity

The Exilis Elite platform uses monopolar radiofrequency (RF) to deliver results in only two to three treatment sessions, according to the company. The device gives uniform and precise distribution of heat, with an advanced cooling system that allows for layering RF energy at various depths.

The Exilis Elite is effective for treating wrinkles and skin laxity in the mid- to lower face. The treatment platform utilizes a reengineered energy flow control system designed to improve patient safety and ensure predictable results, the company states. The Elite applicator monitors impedance multiple times every second and powers off if needed.

For more information:
www.exilis.com

TOPIX

Lotion brightens skin

The ReBrightalyze Enhancement Therapy lotion is a medical-grade moisturizing base that is rich in antioxidants and contains no hydroquinone. The lotion won't clog pores and is free of the bleach smell that can be associated with other skin brightening products, according to the company.

The product reduces the appearance of dark spots, improving skin tone and texture. It is lightweight, fast-absorbing and acetone-free. ReBrightalyze contains a transdermal penetrating system that ensures the optimal delivery of active ingredients, maximizing the lotion's effectiveness, the company says.

Ingredients include kojic acid, arbutin and bearberry, tetrahexyldecyl ascorbate, emblica, ascorbic acid and vitamin E. The combination of botanical ingredients along with antioxidants allows the lotion to improve the skin's appearance while also treating discoloration.

The lotion is safe for long-term use and is appropriate for all skin types.

For more information:
www.topixpharm.com

SKINCEUTICALS

Collection enhances in-office procedures

Three products from SkinCeuticals make up its Body Correct range for boosting the results of in-office cosmetic procedures. The formulations are designed to brighten, tighten, smooth and rejuvenate skin, according to the company. The products target areas such as the abdomen, thighs, buttocks, upper arms, neck, chest and hands.

The product line, available at physicians' offices, includes the Body Tightening Concentrate; the Neck, Chest and Hand Repair; and the Body Retexturing Treatment.

The concentrate contains 2.5 percent peptide and 5 percent yeast extract, as well as 2 percent hydrolyzed rice protein, used to counteract the visible effects of collagen breakdown.

The repair formulation features 1 percent hydroxyphenoxy propionic acid and 3 percent vigna aconitifolia. The blend helps to fade age spots and make skin plumper.

With 17 percent hydroxyethyl urea and aminosulfonic acid compound, plus 4 percent niacinamide and hyaluronic acid, the retexturing treatment targets skin smoothness and moisture levels. It complements laser hair removal and skin resurfacing procedures.

For more information:
www.skinceuticals.com

LUMENIS

Module treats scars, stretch marks

The ResurFX, a module for the M22 device, performs nonablative skin resurfacing for the treatment of acne scars, stretch marks, surgical scars and periorbital wrinkles.

The device's 1,565 nm laser energy is delivered in a nonsequential pattern allowing for increased patient comfort. The module extends the ability of the M22 device, which is a multitechnology platform.

The module has more than 600 parameter combinations. The ResurFX was launched at the American Academy of Dermatology annual meeting in Miami. It has yet to be cleared by the Food and Drug Administration.

For more information:
www.lumenis.com

GLYTONE

Peels target back, chest area

The Glytone by Enerpeel BC Peel System is a comprehensive in-office protocol designed to maximize peel results. The system includes preparatory solution wipes, spray bottles with the peel solution, an ergonomic roller and remover wipes.

With 30 percent salicylic acid, ethyl linoleate, triethyl citrate and GT-Peptide-10, the system targets sebum production and the bacteria that cause acne, according to the company.

The spray bottle delivery system allows for coverage of extensive areas such as the back. The products help to reduce whiteheads and blackheads, and can improve the appearance of lesions caused by acne. The peel system is available exclusively at physicians' offices.

For more information:
www.glytone-usa.com

MDSOLARSCIENCES

Sun and skin care lines offer protection

MDSolarSciences sun care products use safer, natural mineral-derived and organic-based sunscreen actives blended with ProVention-R antioxidants.

At the skin care line's core is the ProVention-R technology and formulations that deliver antioxidants, pigment-modifying agents, biomimetic moisturizers and humectants, and collagen-signaling peptides to the skin through a ProVention-R liposome complex. The line's technology enables users to protect skin while enhancing its youthful, vibrant, glow.

Combined, MDSolarSciences sun care and skin care lines help lower the incidence of melanoma/skin cancer and the appearance of photo damage signs caused by years of often unprotected sun exposure.

For more information:
www.mdsolarsciences.com

GLOTHERAPEUTICS

Treatment for back acne tackles blemishes

The new Back Acne Treatment is designed to treat blemishes while aiding in prevention of the growth of acne-causing bacteria.

The treatment spray contains ingredients such as salicylic acid, to stimulate exfoliation, clear pores, and promote new cell growth, and sodium

To have information about your company's product or service considered for this section, send news releases and photos to:
New Products and Services
Dermatology Times
24950 Country Club Blvd.
Suite 200
North Olmsted, OH 44070
or fax to (800) 788-7188

Publication is subject to space availability and appropriateness, at the editors' discretion.

chlorite to break up sebum and bacteria, while stopping regrowth and reappearance of new bacteria. Disodium EDTA binds free radicals and impurities to enable active ingredients to work effectively. Spearmint oil acts as an antibacterial and antioxidant to help clear acne, dermatitis, and congested skin.

The 360-degree sprayer reaches all body parts to lightly mist all problem areas. Apply up to twice daily on clean skin and let dry before dressing.

For more information:
www.gloprofessional.com

ONSET DERMATOLOGICS

Anti-itch hydrogel targets dermatitis

The new Aurstat anti-itch hydrogel is a treatment for itch, including itch related to atopic dermatitis. Aurstat contains HOCl (hypochlorous acid) as a preservative.

Aurstat is designed to soothe itching, burning, and pain of atopic dermatitis and various dermatoses. The hydrogel formulation is alcohol free, fragrance free, non-irritating, non-sensitizing, and non-cytotoxic. The product is not only safe to use on the face and around the eyes, but it also has no age restrictions.

Aurstat anti-itch hydrogel 225 mL is available in the United States by prescription only.

For more information:
www.onsetdermatologics.com

SOLTA MEDICAL

Treatment tip applies to face, neck

The Thermage Total Tip 3.0 treatment tip for face and neck and other body treatments provides targeted, uniform, bulk heating. It allows dermatologists to treat patients effectively while maintaining patient comfort.

Thermage uses radiofrequency technology to non-invasively help smooth, and contour the skin and temporarily reduce appearance

of cellulite in a single treatment with little to no downtime. The Thermage Total Tip is effective for facial treatments because it delivers uniform, volumetric bulk heating. This heat is dispersed through the vascular structures, which are more prominent on the face than other body areas. This dispersal and uniformity of energy allows for increased patient tolerability and allows practitioners to deliver an efficient heat volume on the face with positive outcomes.

For more information:
www.thermage.com

NEUTROGENA

Sunscreens apply to whole family

The new Neutrogena Beach Defense sunscreens, applicable to the face and body, are made for the whole family. The sunscreens are powerful enough to protect the entire family from the sun's most damaging rays.

Neutrogena Beach Defense sunscreen line, formulated with Helioplex technology, forms a broad spectrum UVA and UVB protective barrier. Ideal for active families, Neutrogena Beach Defense sunscreen line includes large spray and lotion forms that absorb quickly into the face and body without any greasy residue afterward.

Neutrogena Beach Defense sunscreen spray SPF 30 and 70 is sweat- and water-resistant for 80 minutes, has a light fragrance, is oil-free, PABA free and hypoallergenic, and comes in a larger family-value size.

Neutrogena Beach Defense sunscreen lotion SPF 30 and 70 offers a water-resistant protective barrier on skin; is sweat- and water-resistant for 80 minutes; contains a light fragrance; comes in a larger family-value size; and is oil-free, PABA free and hypoallergenic. There is also a travel-friendly Neutrogena Beach Defense sunscreen lotion SPF 70.

For more information:
www.neutrogena.com/category/sun/beach+defense-.do

BABOR

Body cellular system improves skin firmness

The new Babor Body Cellular System helps women achieve a smoother, toned body. The three products in the collection feature an exclusive 3D active complex comprised of hexapeptide-39, forskolin and caffeine to significantly improve firmness and diminish the appearance of cellulite and stretch marks.

Ultimate 3D Cellulite Fluid Ampoule contains a concentrated dose of the 3D active complex to improve the appearance of cellulite. Collagen booster peptide assists in promoting firmness of the connective tissue.

Ultimate 3D Cellulite Lotion is firming and contains caffeine to help reduce fat deposits while chlorella vulgaris, a form of green algae, stimulates circulation and collagen production. Collagen booster peptide helps achieve firmness of connective tissue. Ultimate Forming Body Cream is formulated for women who have stretch marks after pregnancy or significant weight loss. This rich cream regenerates skin to help improve elasticity. The active ingredient tripeptide-1 helps stimulate elastin production while chlorella vulgaris evens pigmentation and promotes collagen production.

For more information:
www.babor.com

upcoming events

Dermatology Times lists meeting announcements for the following three months in our print issue.

Anti-Aging Medicine World Congress — Eastern Europe 2013
www.euromedicom.com
June 14-15, 2013
Moscow

Cosmetic Bootcamp — Didactic and Live Technique Symposium
www.cosmeticbootcamp.com
June 20-23, 2013
St. Regis Aspen Resort
Aspen, Colo.

EAACI-WAO World Allergy & Asthma Congress 2013
www.eaaci-wao2013.com
June 22-26, 2013
Milano Convention Centre
Milan, Italy

Canadian Dermatology Association Annual Conference
www.dermatology.ca
June 27-30, 2013
Quebec City Convention Centre
Quebec City, Quebec, Canada

Society of Dermatology Physician Assistants Annual Summer Conference
www.dermpa.org
June 27-30, 2013
Hyatt Regency at the Arch
St. Louis

Society for Pediatric Dermatology 39th Annual Meeting
www.pedsderm.net
July 11-14, 2013
Pfister Hotel
Milwaukee

8th World Congress of Melanoma
www.worldmelanoma2013.org
July 18-20, 2013
Congress Center Hamburg, Germany

American Academy of Dermatology 2013 Summer Meeting
www.aad.org
July 31-Aug. 3, 2013
New York

Controversies & Conversations in Laser and Cosmetic Surgery
www.skincarephysicians.net
Aug. 9-11, 2013
St. Regis Monarch Beach Resort,
Dana Point, Calif.

Pacific Dermatologic Association 65th Annual Meeting
www.pacificderm.org
Aug. 14-18, 2013
The Palace Hotel
San Francisco

American Dermoscopy Meeting
www.americandermoscopy.com
Aug. 15-17, 2013
The Lodge at Whitefish Lake
Whitefish, Mont.

International Society for Dermatologic Surgery 34th Annual Meeting
www.isdsworld.com
Aug. 29-31, 2013
Valamar Hotel Lacroma Dubrovnik
Dubrovnik, Croatia

American Academy of Dermatology Association 2013 Legislative Conference
www.aad.org
Sept. 8-10, 2013
Willard Intercontinental Hotel
Washington

Alabama Dermatology Society Seminar at Sea
www.alabamaderm.org
Sept. 11-19, 2013
Crystal Cruise Line - Crystal Serenity
Barcelona, Spain

9th Annual Coastal Derm Symposium
www.coastalderm.org
Sept. 25-28, 2013
Willows Lodge, Woodinville, Washington

American Society for Dermatologic Surgery Annual Meeting
www.asds.net
Oct. 3-6, 2013
Hyatt Regency Chicago, Ill.

For a full listing of events, go to *www.dermatologytimes.com*

ad index

This index is provided as an additional service.
The publisher does not assume any liability for errors or omissions
* Indicates demographic advertisement

Go to: products.modernmedicine.com **Products & Services** SHOWCASE

EDUCATION

MEMBERSHIP

SERVICES

LEAVITT Search

AMERIDERM

a division of **Advanced Dermatology & Cosmetic Surgery**

Grow More. *Practice More.*℠

Coding. Billing. Collections.

Ameriderm is a premier practice management service, created by a dermatologist specifically for dermatology practices.

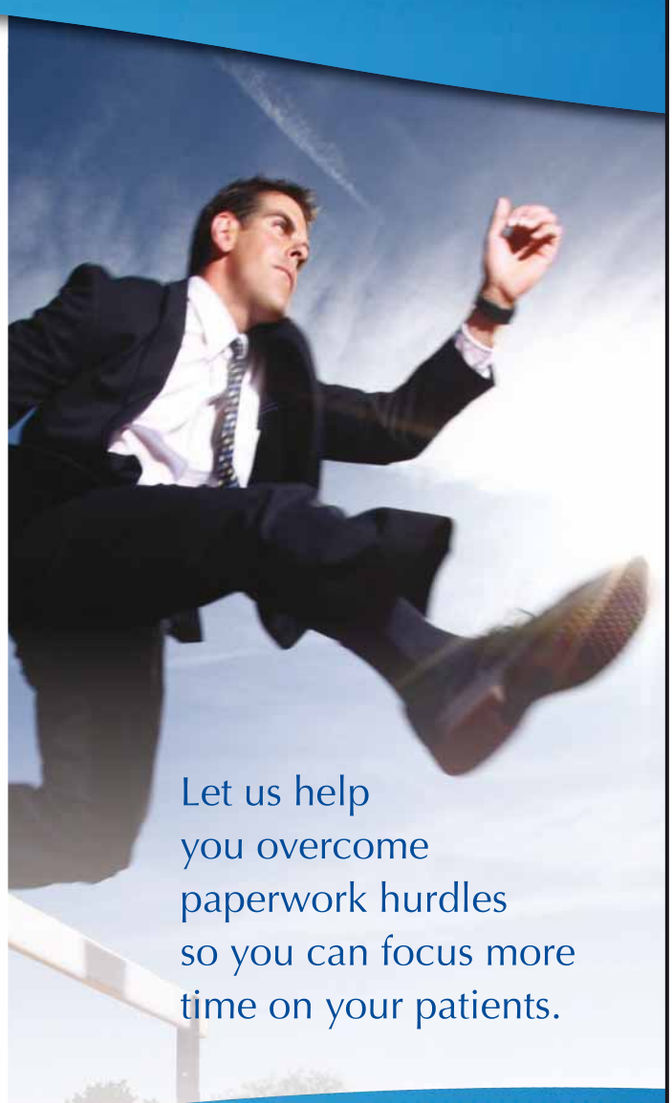
- Best collection rates in the business and the lowest fees
- Collections received and paid in < 20 days
- Collect > 97% of contractually allowed service charge
- All hardware, software, training and support included

Additional benefits of Ameriderm:

Access to our heavily discounted rates for:

- Medical and office supplies (McKesson and Office Depot)

- **NOW OFFERING: Medical Malpractice Insurance (A++ Ratings)**



Let us help you overcome paperwork hurdles so you can focus more time on your patients.

Contact David Morell for a FREE customized review and proposal.

Ph: 407-875-2090 Ext. 1244

or at

dmorell@leavittmgt.com

PRODUCTS & SERVICES

EQUIPMENT FOR SALE

2012 LIPOSONIX machine by Solta Medical for Sale

Minimally used, excellent condition and still under warranty
Asking $69,000, OBO
Contact Barbara:
305-751-7771

FOR SALE BY DERMATOLOGIST

- Save Thousands on These Great Non-Invasive Cosmetic Devices.
- Barely Used Zeltiq Coolsculpting with 6.3 & 8 Handpieces New over $90,000 Barely Used for $70,000 OBO.
- Barely Used Exilis Radiofrequency (2 handpieces) for Skin Tightening/ Fat Contouring.
- New retail $85,000
- Barely used $53,000 OBO.

Call 561-276-3111
or email:
leslie@dermasurgerygroup.com

Cynosure Cellulaze/Triplex/ Smartlipo Machine

Practically new – Only used twice Still under warranty. Free training session included. Available for thousands under new unit price just take over payments.

Please contact plasticsurgerysf@yahoo.com

MARKETPLACE ADVERTISING

Call Karen Gerome to place your Marketplace ad at 800.225.4569 ext. 2670 kgerome@advanstar.com

PRACTICE FOR SALE

NATIONAL

INTEGRATED DERMATOLOGY GROUP

We Buy Practices

- Retiring
- Monetization of your practice
- Locking in your value now
- Succession planning
- Sell all or part of your practice

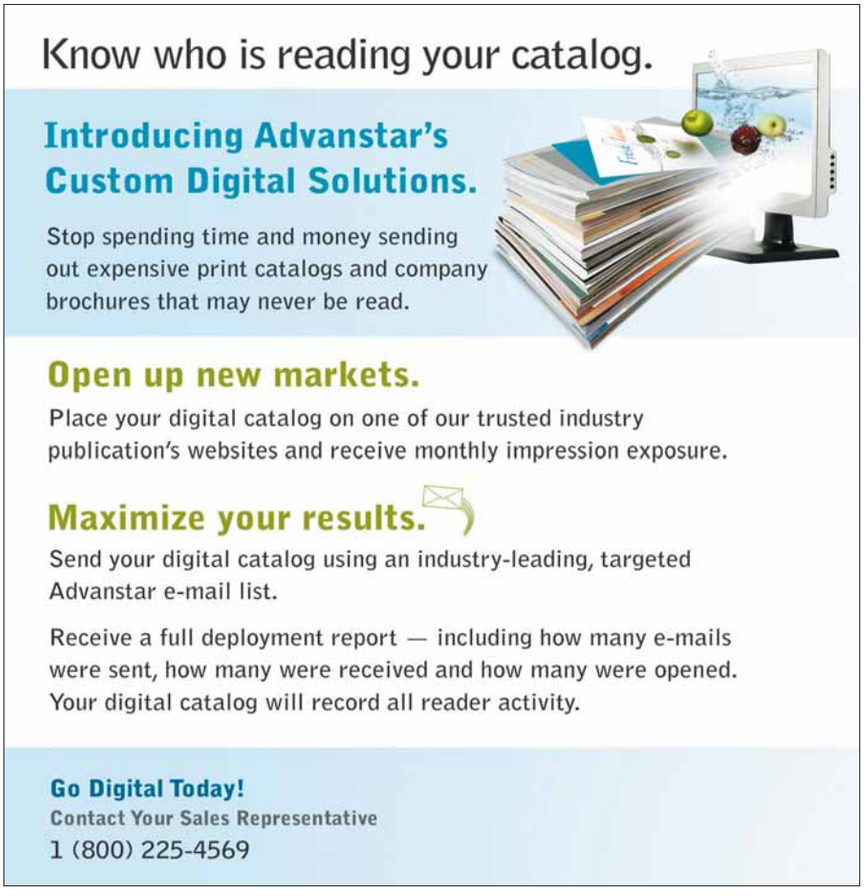
Please call Jeff Queen toll free at (866) 488-4100 or email WeBuy@MyDermGroup.com www.MyDermGroup.com

PRACTICE FOR SALE HAWAII

Long established thriving practice, collecting $3,250,000 + in 2012. Full range of medical, surgical and cosmetic services including Mohs. 100% Bank Financing Available (OAC).

Call 800-416-2055
www.TransitionConsultants.com

PRODUCTS



RECRUITMENT

ARIZONA

ARIZONA

Practice opportunity in Yuma, the sunniest city in the country and a short drive from San Diego. Established successful practice with great payor mix seeking BC/BE Dermatologist. Work under contract with option to purchase practice.

Contact Greg Ertl at
gertl4540@hotmail.com or 928-271-9662

CALIFORNIA

BC/BE Dermatologist to join a busy dermatology practice with Arch Health Partners, an award winning multispecialty group in San Diego.

Please send CV to Catherine.jones@archhealth.org

PORTERVILLE, CA
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/
INTEGRATED DERMATOLOGY GROUP

COLORADO

MONTROSE COLORADO
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/
INTEGRATED DERMATOLOGY GROUP

FLORIDA

WEST PALM BEACH, FL
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/
INTEGRATED DERMATOLOGY GROUP

FT. LAUDERDALE, FLORIDA
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/
INTEGRATED DERMATOLOGY GROUP

CLASSIFIED WORKS!

LOUISIANA

Ochsner Health System

DERMATOLOGY

OCHSNER HEALTH SYSTEM BATON ROUGE has opportunities for the following Dermatologists. Medical Dermatologists with an interest in Cosmetic Dermatology are welcomed to apply. Salary offered will be $350k and up for Chair, and $325k and up for Staff, depending upon training and experience.

- **DEPARTMENT CHAIR -** The successful candidate will be a board-certified, outstanding clinician with significant, demonstrated competency in leadership with a visionary approach.
- **STAFF DERMATOLOGIST** - BC/BE candidates with experience or directly from training are welcomed to apply.

The Greater Baton Rouge region has over 1,400 employees serving our patients in nine Ochsner Health Centers and Ochsner Medical Center Baton Rouge, a 201-bed facility. We employ more than 130 physicians and mid-level providers who provide an excellent referral base.

Baton Rouge, the state capital, represents the best of Louisiana's vibrant culture. The community provides numerous cultural, educational, historical, and recreational activities and is known for friendly people and unique food. The Baton Rouge metropolitan area has a population of over 600,000 and is home to Louisiana State University and Southern University.

Ochsner Health System is a physician-led, non-profit, academic, multi-specialty healthcare delivery system dedicated to patient care, research, and education. Our mission is to Serve, Heal, Lead, Educate, and Innovate. The system includes eight hospitals and more than 38 health centers throughout Southeast Louisiana. Ochsner employs over 900 physicians representing all major medical specialties and subspecialties. We conduct over 300 ongoing clinical research trials annually. We offer a generous and comprehensive benefits package. We also enjoy the advantage of practicing in a favorable malpractice environment in Louisiana. Please visit our website, **www.ochsner.org.**

Please email CV to: profrecruiting@ochsner.org,
Ref. #ADCSS02 or call 800-488-2240 for more information. EOE.
Sorry, no J1 visa opportunities available.

NEW HAMPSHIRE

NEW HAMPSHIRE
Seeking Mohs Surgeon P/T, 2 days per month.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/
INTEGRATED DERMATOLOGY GROUP

NEW JERSEY

DERMATOLOGIST

General/Cosmetic/Surgical Dermatology
Medford, NJ (near Philadelphia, PA and Cherry Hill, NJ). Brand new state of the art office, fabulous opportunity, benefits offered. FT/PT position available.
Email inquiry or CV to: suzanne@accentderma.com

ADVERTISE TODAY

Call
Joanna Shippoli
to place your
Recruitment ad at
800.225.4569,
ext. 2615
jshippoli@advanstar.com

RECRUITMENT

NEW YORK

Flushing, Queens, NYC

Very busy 2 physician practice seeking full or part time BC/BE Dermatologist and Physician's Assistant.

Mix of general medical/surgical and cosmetic derm. Preferably bilingual Chinese or Spanish. Highly competitive compensation and benefits.

Email CV: skindoc98@yahoo.com

BRONX, MANHATTAN, NYC

- *Retired?*
- *Looking to go Part Time?*
- *Thinking about Retirement?*
- *Looking to spend more time with the family?*

Well established, thriving, multi-center Dermatology practice seeking a Supervising Dermatologist with limited patient care responsibilities. Highly competitive compensation.

EMAIL CV: CPSDOCS@yahoo.com

DERMATOLOGIST

Garden City Dermatology
Long Island, New York

Full-service dermatology practice, for 30 years, offering adult, pediatric, surgical (including Mohs) and cosmetic care. Our physicians are board certified in dermatology, pediatric dermatology & dermatopathology. Our Director is triple board certified. We are seeking a board-certified or board-eligible provider for full or part-time work. We offer an excellent benefits package. Located in a beautiful new, bright, spacious suite, only ½ hour from Manhattan. Latest equipment including CO2, ICON, Vectus, Alex, Nd:YAG, Smart, Pulse Dye, Cynergy, Xtrac, UV, Revage, Dermasweep, and others.

Interviews arranged thru
Melodie@GardenCityDerm.com
(516) 227-3377

PENNSYLVANIA

BC/BE Dermatologist
PENNSYLVANIA

Well-established, thriving practice with 7 dermatologists seeks ***BC/BE Dermatologist***.
State of the art 12,000 sq. ft. new facility with in-house Mohs, dermatopathology, aesthetic services, lasers and phototherapy. Excellent benefits, malpractice, health insurance, vacation/CME. Partner buy-in after 2 years. Located in a rapidly-growing, affluent, family-oriented community with a population of 519K.

Call Bonnie Oberholtzer at
(717) 509-5968
or e-mail to: blo@dermlanc.com

DERMATOLOGY ASSOCIATES OF LANCASTER

TENNESSEE

MURFREESBORO, TN
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/

INTEGRATED DERMATOLOGY GROUP

TEXAS

DALLAS, TEXAS
Partnership available. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/

INTEGRATED DERMATOLOGY GROUP

WASHINGTON DC

WASHINGTON, DC
Seeking associate. Established practice.
Contact Jeff Queen, (866) 488-4100 or
http://mydermgroup.com/wp2/become-a-partner/

INTEGRATED DERMATOLOGY GROUP

TOP MEDICAL APPS

Mobile tech your patients may be using this year

By Gretchyn M. Bailey, NCLC, FAAO
Staff Correspondent

The use of mobile technology to deliver healthcare services and information skyrocketed in 2012. Some 44 million health apps will have been downloaded by the end of this year (predicted to reach 142 million downloads by 2016),[1] and consumers are now spending $700 million per year on these apps.[2] There are more than 10,000 health apps in the iTunes app store,[3] the number of American using smartphones for health information grew from 61 million to 75 million in 2012,[2] and 88% of doctors would like patients to monitor their health at home.[3]

Here are a few medical and health apps your patients may be using this year.

MediSafe Project

MediSafe Project is the first-ever cloud-synced pillbox app that not only reminds you when it's time to take your medication, but also sends your family, friends, and caretakers alerts if you miss a dose, leveraging the power of your support system to keep you healthier. Compatible with the FDA's drug database, generic and brand name medications autocomplete as users enter them—automatically recording the correct pharmaceutical name, manufacturer, and medication strength. Or, use your smartphone's camera to snap the FDA's universal National Drug Code (NDC) number, found on all original pharmaceutical packaging, to enter a medication. *http://medisafeproject.com*

EveryoneEat!

EveryoneEat! helps the 150 million Americans living with a chronic condition or dietary restriction find restaurants serving meals appropriate for them. By partnering with nationally recognized health associations, clinical and registered dietitians, and thousands of your favorite restaurants, the app finds dishes that meet your dietary needs and displays them by cuisine type or restaurant name. Simply enter your age, height, weight, gender, and activity level, and the app is ready to use. *http://foodcalc.com/everyoneeat*

WebMD Pain Coach

WebMD Pain Coach helps people with chronic pain conditions make daily health and wellness choices so they can manage their pain smarter. From back pain to migraines, the app lets you record daily pain levels, export your pain history to PDF, and e-mail it to your doctor. You can also select doctor-approved goals from five lifestyle categories related to your pain condition(s): Food, Rest, Exercise, Mood, and Treatments, view "bite-sized" tips matched with your goals and organized by lifestyle categories, and read hundreds of articles, videos, slideshows, and quizzes on pain management related to your condition(s). *www.webmd.com/a-to-z-guides/video/pain-coach-long*

Emergency Kit

Emergency Kit is an easy way to aggregate all of your most critical information—and could save your life in a medical emergency. Emergency technicians will be able to view your vital stats including blood type, allergies, medications, and emergency contacts within the app. It can also turn your phone into an SOS light beacon, send out an emergency text message or e-mail with your GPS coordinates, or look up how to treat a variety of injuries. *http://startlab.us/emergency-kit* **DT**

Mobile healthcare delivery skyrocketed in 2012

44 MILLION health apps will have been downloaded by the end of the year (predicted to reach 142 million downloads by 2016)[1]

$700 MILLION consumers are now spending per year on these apps[2]

10,000 health apps in the iTunes app store[3]

61 MILLION TO 75 MILLION growth this year in the number of American using smartphones for health information[2]

88% of doctors would like patients to monitor their health at home[3]

Sources: iHealthBeat, Healthcare IT News, and MedNEWS Blog.

References

1 44M mobile health apps will be downloaded in 2012, report predicts. iHealthBeat. http://www.ihealthbeat.org/articles/2011/12/1/44m-mobile-health-apps-will-be-downloaded-in-2012-report-predicts.aspx. Accessed Feb. 21, 2013.

2 Pennic F. 45 mind blowing digital health statistics and trends. Healthcare IT News. http://www.healthcareitnews.com/blog/45-mind-blowing-digital-health-statistics-and-trends. Accessed Feb. 21, 2013.

3 Conti K. How the explosion of mobile health is changing healthcare. MedNEWS Blog. http://www.mednet-tech.com/newsletter/mobile-marketing/how-the-explosion-of-mobile-health-is-changing-healthcare. Accessed Feb. 21, 2013.

IMPORTANT INFORMATION ABOUT

Oracea®

(doxycycline, USP) 40 mg* Capsules

***30 mg Immediate Release & 10 mg Delayed Release beads**

BRIEF SUMMARY

This summary contains important information about ORACEA (Or-RAY-sha). It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking ORACEA. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ORACEA. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS ORACEA?

ORACEA is a prescription medicine to treat only the pimples or bumps on the face caused by a condition called rosacea. ORACEA is not an antibiotic dose of doxycycline and should not be used for the treatment of infections. ORACEA did not lessen the facial redness caused by rosacea. ORACEA has not been studied for the treatment of rosacea of the eyes or of small blood vessels in the skin. It is not known if ORACEA is effective for use for longer than 16 weeks and it is not known if ORACEA is safe for use longer than 9 months.

WHO IS ORACEA FOR?

ORACEA is for use in adults.

ORACEA should not be given to infants and children 8 years or younger because it may cause staining during tooth development that will not go away.

Also, do not take ORACEA if you are allergic to any medicine known as a tetracycline, including doxycycline and minocycline. If you are not sure, talk to your doctor or pharmacist.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING ORACEA?

Tell your doctor about all your health conditions, especially if you

- have had an allergic reaction to doxycycline or other medicines known as tetracyclines.
- are pregnant or planning to become pregnant. ORACEA may harm your unborn baby.
- are breastfeeding. ORACEA passes into breast milk and may harm your baby.
- have kidney problems.
- have liver problems.
- have had surgery on your stomach.
- have or had a yeast or fungus infection in your mouth or vagina.
- spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. Although sensitivity to sunlight has not been observed in controlled clinical studies of ORACEA, tetracycline-class products can cause you to get severe sunburns.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

ORACEA and other medicines can affect each other causing serious side effects. Especially tell your doctor if you take

- blood thinners (anticoagulants), such as warfarin or Coumadin®. Your doctor may need to change your anticoagulant dose.
- any medicine to treat pimples (acne) or psoriasis.
- birth control pills. Talk to your doctor about other methods of birth control because birth control pills may not work as well when you are taking ORACEA.
- proton pump inhibitors or antacid medicines containing calcium, magnesium or aluminum.
- products containing iron or bismuth subsalicylate.
- any medicine to treat an infection, such as penicillin.
- any medicine to treat seizures.

WHAT SHOULD I AVOID WHILE TAKING ORACEA?

- Although sensitivity to sunlight has not been observed in controlled clinical studies of ORACEA, you should not spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. You could get a severe sunburn. Use sunscreen and wear clothes that cover your skin if you have to be in sunlight.
- You should not take ORACEA if you are pregnant or breast feeding or are a man or a woman trying to have a baby.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF ORACEA?

Common side effects of ORACEA are soreness in the nose and throat, diarrhea, sinus infection, high blood pressure, and increase in aspartate aminotransferase in the blood.

ORACEA may also cause

- darkening of your skin, scars, teeth, or gums
- severe headaches, dizziness, or double vision from high pressure in the fluid around the brain

ORACEA may cause serious side effects. Stop taking ORACEA and talk to your doctor right away if you

- have any skin rash, redness, or unusual or severe sunburn
- have an allergic reaction, which may cause a skin rash, swelling, difficulty swallowing, or a feeling of tightness in your throat
- become pregnant
- have stomach cramps, high fever, and bloody diarrhea
- have fever, rash, joint pain, and feel tired. These may be symptoms of a problem where your body is attacking itself (autoimmune syndrome)

These are not all of the possible side effects of ORACEA. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch or call 1-800-FDA-1088*. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

HOW SHOULD I TAKE ORACEA?

- Take ORACEA exactly as prescribed by your doctor. Do not change your dose unless told to do so by your doctor. Taking more than the prescribed dose may increase your chance of having side effects.
- The usual dose of ORACEA is one capsule in the morning on an empty stomach. You should take ORACEA at least one hour before or two hours after a meal.
- Take ORACEA with a full glass of water while sitting or standing. To prevent irritation to your throat, do not lay down right after taking ORACEA.
- Do not take ORACEA with or right after taking antacids or products that contain calcium, aluminum, magnesium, or iron. ORACEA may not work as well.
- If you take too much ORACEA, or overdose, stop taking ORACEA and talk to your doctor.
- If you miss a dose of ORACEA, skip that dose and take the next dose at your regular time.
- Do not take ORACEA to treat infections caused by bacteria, germs or viruses.
- Your doctor may do blood tests from time to time to check for side effects of ORACEA.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT ORACEA?

- Talk to your doctor or pharmacist
- Go to **www.oracea.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA

Revised: February 2013

References: 1. Data on file. Galderma Laboratories, L.P. **2.** Del Rosso JQ, Schlessinger J, Werschler P. Comparison of anti-inflammatory dose doxycycline versus doxycycline 100 mg in the treatment of rosacea. *J Drugs Dermatol.* 2008;7(6):573-576. **3.** Preshaw PM, Novak MJ, Mellonig J, et al. Modified-release subantimicrobial dose doxycycline enhances scaling and root planing in subjects with periodontal disease. *J Periodontol.* 2008;79(3):440-452.

Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
ORA-879 Printed in USA 05/13

hcp.oracea.com

GALDERMA
Committed to the future of dermatology

Once-daily 40 mg Capsules*
Oracea®
(doxycycline, USP) *30 mg immediate release & 10 mg delayed release beads

Help break the unpredictable cycle of rosacea…

CONTAIN THE FLARE OF INFLAMMATION

STRIKE BACK WITH ORACEA®

Oracea® (doxycycline, USP) Capsules, 40 mg:

- Formulated for an effective anti-inflammatory response—30 mg immediate and 10 mg delayed release beads[1]
- Efficacy equivalent to doxycycline 100 mg with fewer GI side effects[2]*
  —In pivotal clinical studies, the most common GI side effect was diarrhea (4.5%)[1]
- No evidence of bacterial resistance in a 9-month safety study[3†]

Important Safety Information

Indication: ORACEA® is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. ORACEA® does not lessen the facial redness caused by rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with ORACEA® were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase increase. **Warnings/Precautions:** ORACEA® should not be used to treat or prevent infections. ORACEA® should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA® should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA® patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA® treatment beyond 16 weeks and safety beyond 9 months have not been established.

You are encouraged to report negative side effects of prescription drugs to the FDA. *Visit www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

*A randomized, multicenter, outpatient, double-blind, active-controlled, noninferiority trial of 91 rosacea patients (≥18 years of age) over 16 weeks. Patients were prospectively randomized to receive daily doses of either 40-mg Oracea® or 100-mg doxycycline, each with metronidazole 1%.[2]

†A randomized, multicenter, double-blind, placebo-controlled, parallel-group study of 266 patients (≥18 years of age) was conducted to evaluate the efficacy of 40-mg Oracea® as an adjunct to scaling and root planing for the treatment of periodontitis over a 9-month period. Patients were evaluated at 3, 6, and 9 months after baseline visit.[3]

START WITH
Once-daily 40 mg Capsules*
Oracea®
(doxycycline, USP) *30 mg immediate release & 10 mg delayed release beads

AT THE FIRST SIGN OF INFLAMMATORY ROSACEA

SUPPLEMENT TO
Dermatology Times®
News and Analysis for Today's Skincare Specialists

JUNE 2013
Vol. 34, Supp.2

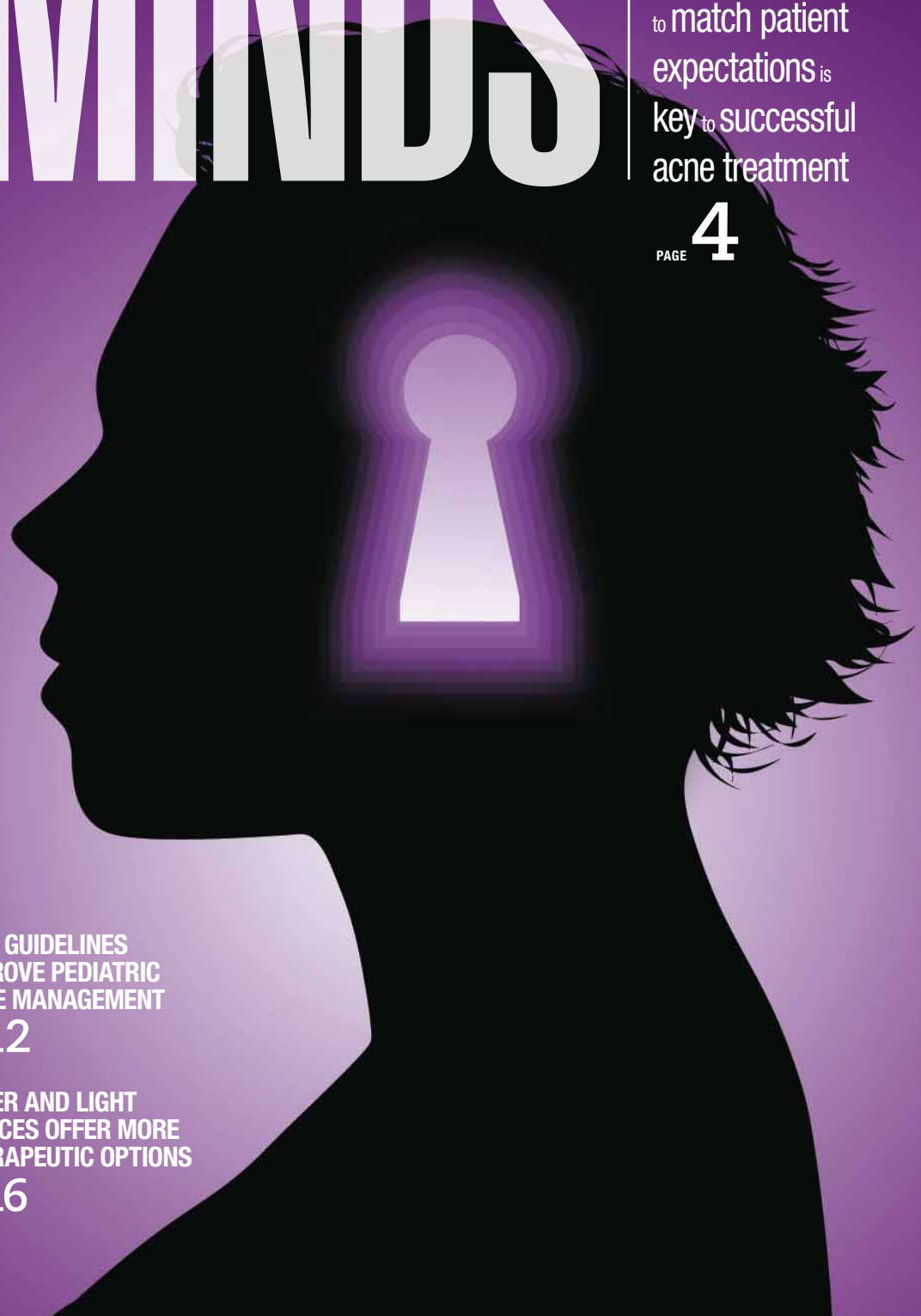
DermatologyTimes.com

A MEETING OF MINDS

Shaping therapeutic interventions to match patient expectations is key to successful acne treatment

PAGE 4

ACNE+



NEW GUIDELINES IMPROVE PEDIATRIC ACNE MANAGEMENT

PAGE 12

LASER AND LIGHT DEVICES OFFER MORE THERAPEUTIC OPTIONS

PAGE 16

ADVANSTAR
MEDICAL COMMUNICATIONS GROUP

Achieve harmony in acne management

Cetaphil® DermaControl™ Foam Wash and Moisturizer SPF 30

for patients with acne-prone skin

CONTROL oil with a highly tolerable regimen formulated with advanced zinc technology[1-4]

PROTECT with an SPF 30 moisturizer and help restore skin barrier function with ceramide technology[5]

BALANCE control of both acne symptoms and acne treatment effects[1]*

*Formulated to be used with acne treatments.

References: 1. Data on file. Galderma Laboratories. **2.** Bigotti C, Guala F, Merlo E, Gazzaniga G, Villa G. Zinc and its derivatives: their applications in cosmetic. *J Appl Cosmetol.* 2005;23:139-147. **3.** Rigano L, Merlo E, Guala F, Villa G. Stabilized solutions of zinc coceth sulfate for skin cleansing and skin care. *Cosmetics Toiletries.* 2005;120:103-108. **4.** Schwartz JR, Marsh RG, Draelos ZD. Zinc and skin health: overview of physiology and pharmacology. *Dermatol Surg.* 2005;31:837-847. **5.** Castiel-Higounenc I, Chopart M, Ferraris C. Stratum corneum lipids: specificity, role, deficiencies and modulation. *OCL.* 2004;11(6):401-406.

cetaphil.com

GALDERMA
Committed to the future of dermatology

Galderma Laboratories, L.P., 14501 N. Freeway, Fort Worth, TX 76177
CETA-629 Printed in USA 03/13

Cetaphil® DERMACONTROL™

Control. Protect. Balance.

SUPPLEMENT TO

Dermatology Times®

News and Analysis for Today's Skincare Specialists

www.DERMATOLOGYTIMES.com

TRENDING ONLINE

Group announces new guidelines for treating pediatric acne

The American Acne and Rosacea Society issued the first evidence-based clinical guidelines for the management of acne vulgaris in children and adolescents.

dermatologytimes.com/pedsacne

Low-dose isotretinoin works for adult acne

Oral isotretinoin at 5 mg per day is reportedly as effective, but with fewer side effects, than the standard dose of 0.5-1 mg/kg per day for low-grade adult acne, a study indicates.

dermatologytimes.com/isotretinoin

Experimental laser targets sebaceous glands to treat acne

Selective photothermolysis of the sebaceous glands could be an effective future therapy for acne.

dermatologytimes.com/acnelaser

sign up for Dermatology Times' weekly newsletter!
MODERNMEDICINE.COM/DERMATOLOGYTIMES/ENEWSGROUP

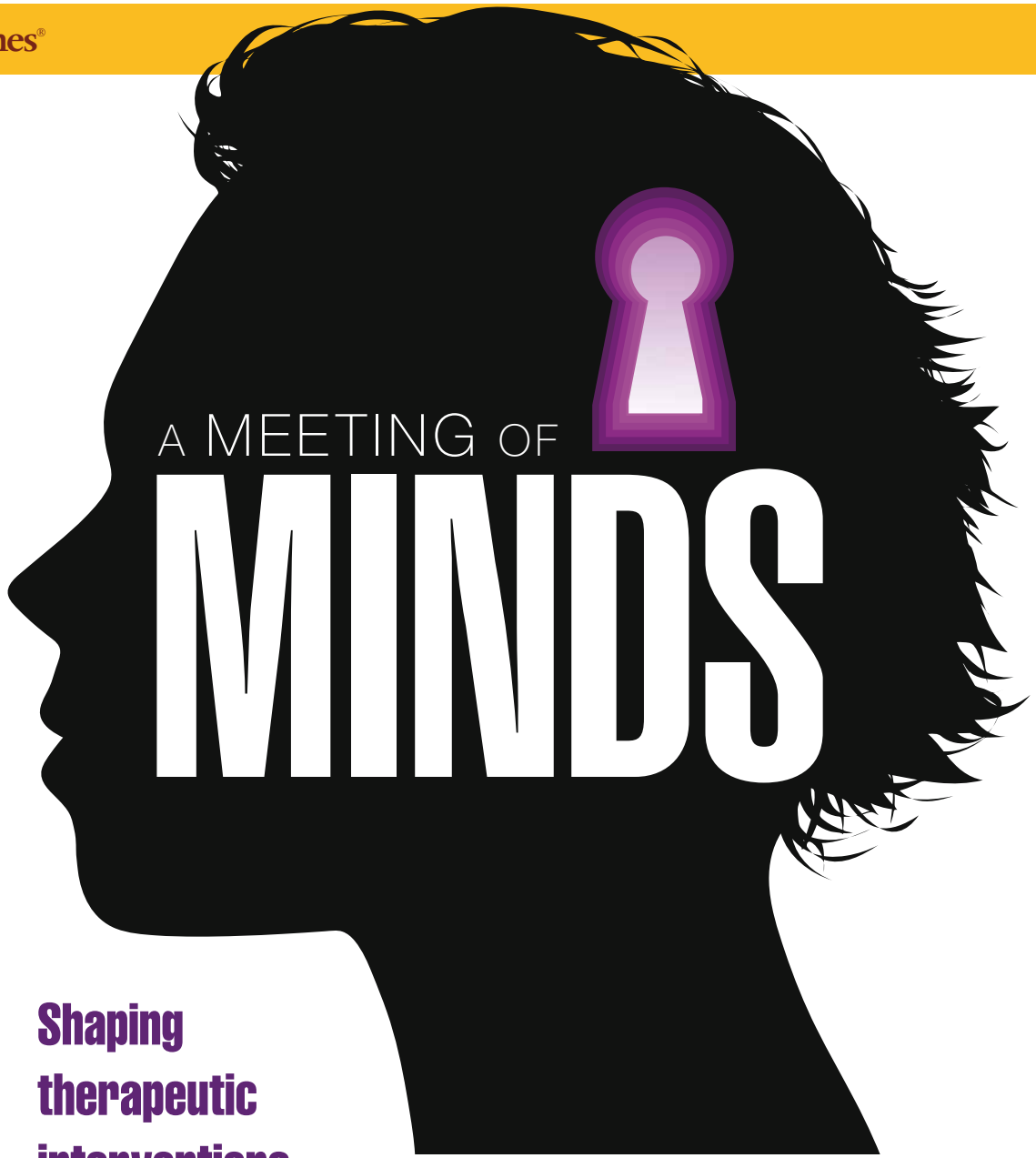
JUNE 2013 | Vol. 34, Supp.2

Follow Us!

twitter.com/dermtimesnow

facebook.com/dermatologytimes

ACNE



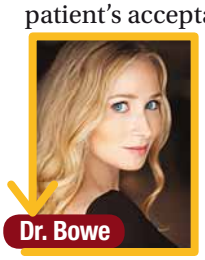
A MEETING OF MINDS

Shaping therapeutic interventions to match patient expectations is key to successful acne treatment

By John Jesitus
Staff Correspondent

Even though patients may present with clinically similar acne, their expectations and preferences for particular treatments may differ vastly, an expert says.

Accordingly, Whitney P. Bowe, M.D., adds "We must tailor our treatment recommendations based on the patient's acceptance of certain interventions, as well as their timeline." Dr. Bowe is a dermatologist in New York City and Westchester, N.Y., and is a clinical assistant professor of dermatology at the State University of New York


Dr. Bowe

CONTINUED ON PAGE 7

Start your acne patients on ACZONE® (dapsone) Gel 5%

Write 90g

Now Available

Write the 90-gram tube and start your patients on a proven active ingredient—dapsone gel 5%. See why 79% of ACZONE® (dapsone) Gel 5% prescriptions are written for females (n = 434,133).[1]

ACZONE® was proven effective in males and females 12 years of age and older.[2]

INDICATION
ACZONE® (dapsone) Gel 5% is indicated for the topical treatment of acne vulgaris.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS
Hematological effects: Oral dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. There was no evidence of clinically relevant hemolysis or anemia in patients treated with ACZONE® Gel 5%, including patients who were G6PD deficient. Some subjects with G6PD deficiency using ACZONE® Gel 5% developed laboratory changes suggestive of mild hemolysis.

If signs and symptoms suggestive of hemolytic anemia occur, ACZONE® Gel 5% should be discontinued. ACZONE® Gel 5% should not be used in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of ACZONE® Gel 5% with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

References: 1. IMS Health, Inc. *Vector One®: National* (VONA). Plymouth Meeting, PA: IMS Health, Inc.; January 2013. **2.** ACZONE® Prescribing Information.

ALLERGAN Medical Dermatology

Re-order: APC21SP13 130866

Peripheral neuropathy: Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical ACZONE® (dapsone) Gel 5% treatment.

Skin: Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These types of skin reactions were not observed in clinical trials with topical ACZONE® Gel 5% treatment.

ADVERSE REACTIONS
The most common adverse reactions of ACZONE® Gel 5% (incidence ≥ 10%) are oiliness/peeling, dryness, and erythema at the application site.

DRUG INTERACTIONS
Topical application of ACZONE® Gel followed by benzoyl peroxide in subjects with acne vulgaris resulted in a temporary local yellow or orange discoloration of the skin and facial hair (reported by 7 out of 95 subjects in a clinical study) with resolution in 4 to 57 days.

Please see brief summary of full Prescribing Information on the adjacent page.

Now available in a 90-gram tube!

ACZONE® (dapsone) Gel 5%

INDICATIONS AND USAGE

ACZONE® Gel, 5%, is indicated for the topical treatment of acne vulgaris.

DOSAGE AND ADMINISTRATION

For topical use only. Not for oral, ophthalmic, or intravaginal use.

After the skin is gently washed and patted dry, apply approximately a pea-sized amount of **ACZONE**® Gel, 5%, in a thin layer to the acne affected areas twice daily. Rub in **ACZONE**® Gel, 5%, gently and completely. **ACZONE**® Gel, 5%, is gritty with visible drug substance particles. Wash hands after application of **ACZONE**® Gel, 5%.

If there is no improvement after 12 weeks, treatment with **ACZONE**® Gel, 5%, should be reassessed.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hematological Effects

Oral dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. G6PD deficiency is most prevalent in populations of African, South Asian, Middle Eastern, and Mediterranean ancestry.

There was no evidence of clinically relevant hemolysis or anemia in patients treated with **ACZONE**® Gel, 5%, including patients who were G6PD deficient. Some subjects with G6PD deficiency using **ACZONE**® Gel developed laboratory changes suggestive of mild hemolysis.

If signs and symptoms suggestive of hemolytic anemia occur, **ACZONE**® Gel, 5% should be discontinued. **ACZONE**® Gel, 5% should not be used in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of **ACZONE**® Gel, 5%, with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

Peripheral Neuropathy

Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical **ACZONE**® Gel, 5% treatment.

Skin

Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These types of skin reactions were not observed in clinical trials with topical **ACZONE**® Gel, 5% treatment.

ADVERSE REACTIONS

Clinical Studies Experience

Because clinical trials are conducted under prescribed 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 practice.

Serious adverse reactions reported in patients treated with **ACZONE**® Gel, 5%, during clinical trials included but were not limited to the following:

- Nervous system/Psychiatric – Suicide attempt, tonic clonic movements.
- Gastrointestinal – Abdominal pain, severe vomiting, pancreatitis.
- Other – Severe pharyngitis

In the clinical trials, a total of 12 out of 4032 patients were reported to have depression (3 of 1660 treated with vehicle and 9 of 2372 treated with **ACZONE**® Gel, 5%). Psychosis was reported in 2 of 2372 patients treated with **ACZONE**® Gel, 5%, and in 0 of 1660 patients treated with vehicle.

Combined contact sensitization/irritation studies with **ACZONE**® Gel, 5%, in 253 healthy subjects resulted in at least 3 subjects with moderate erythema. **ACZONE**® Gel, 5%, did not induce phototoxicity or photoallergy in human dermal safety studies.

ACZONE® Gel, 5%, was evaluated for 12 weeks in four controlled studies for local cutaneous events in 1819 patients. The most common events reported from these studies include oiliness/peeling, dryness, and erythema.

One patient treated with **ACZONE**® Gel in the clinical trials had facial swelling which led to discontinuation of medication.

In addition, 486 patients were evaluated in a 12 month safety study. The adverse event profile in this study was consistent with that observed in the vehicle-controlled studies.

Experience with Oral Use of Dapsone

Although not observed in the clinical trials with **ACZONE**® Gel (topical dapsone) serious adverse reactions have been reported with oral use of dapsone, including agranulocytosis, hemolytic anemia, peripheral neuropathy (motor loss and muscle weakness), and skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria).

DRUG INTERACTIONS

Trimethoprim-Sulfamethoxazole

A drug-drug interaction study evaluated the effect of the use of **ACZONE**® Gel, 5%, in combination with double strength (160 mg/800 mg) trimethoprim-sulfamethoxazole (TMP/SMX). During co-administration, systemic levels of TMP and SMX were essentially unchanged. However, levels of dapsone and its metabolites increased in the presence of TMP/SMX. Systemic exposure (AUC_{0-12}) of dapsone and N-acetyl-dapsone (NAD) were increased by about 40% and 20% respectively in the presence of TMP/SMX. Notably, systemic exposure (AUC_{0-12}) of dapsone hydroxylamine (DHA) was more than doubled in the presence of TMP/SMX. Exposure from the proposed topical dose is about 1% of that from the 100 mg oral dose, even when co-administered with TMP/SMX.

Topical Benzoyl Peroxide

Topical application of **ACZONE**® Gel followed by benzoyl peroxide in subjects with acne vulgaris resulted in a temporary local yellow or orange discoloration of the skin and facial hair (reported by 7 out of 95 subjects in a clinical study) with resolution in 4 to 57 days.

Drug Interactions with Oral Dapsone

Certain concomitant medications (such as rifampin, anticonvulsants, St. John's wort) may increase the formation of dapsone hydroxylamine, a metabolite of dapsone associated with hemolysis. With oral dapsone treatment, folic acid antagonists such as pyrimethamine have been noted to possibly increase the likelihood of hematologic reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally in doses of 75 mg/kg/day and 150 mg/kg/day (approximately 800 and 500 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons), respectively. These effects were probably secondary to maternal toxicity. **ACZONE**® Gel, 5%, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Although systemic absorption of dapsone following topical application of **ACZONE**® Gel, 5%, is minimal relative to oral dapsone administration, it is known that dapsone is excreted in human milk. Because of the potential for oral dapsone to cause adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue **ACZONE**® Gel, 5%, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and efficacy was evaluated in 1169 children aged 12-17 years old treated with **ACZONE**® Gel, 5%, in the clinical studies. The adverse event rate for **ACZONE**® Gel, 5%, was similar to the vehicle control group. Safety and efficacy was not studied in pediatric patients less than 12 years of age, therefore **ACZONE**® Gel, 5%, is not recommended for use in this age group.

Geriatric Use

Clinical studies of **ACZONE**® Gel, 5%, did not include sufficient number of patients aged 65 and over to determine whether they respond differently from younger patients.

G6PD Deficiency

ACZONE® Gel, 5% and vehicle were evaluated in a randomized, double-blind, cross-over design clinical study of 64 patients with G6PD deficiency and acne vulgaris. Subjects were Black (88%), Asian (6%), Hispanic (2%) or of other racial origin (5%). Blood samples were taken at Baseline, Week 2, and Week 12 during both vehicle and **ACZONE**® Gel, 5% treatment periods. There were 56 out of 64 subjects who had a Week 2 blood draw and applied at least 50% of treatment applications. **ACZONE**® Gel was associated with a 0.32 g/dL drop in hemoglobin after two weeks of treatment, but hemoglobin levels generally returned to baseline levels at Week 12.

There were no changes from baseline in haptoglobin or lactate dehydrogenase during **ACZONE**® or vehicle treatment at either the 2-week or 12-week time point.

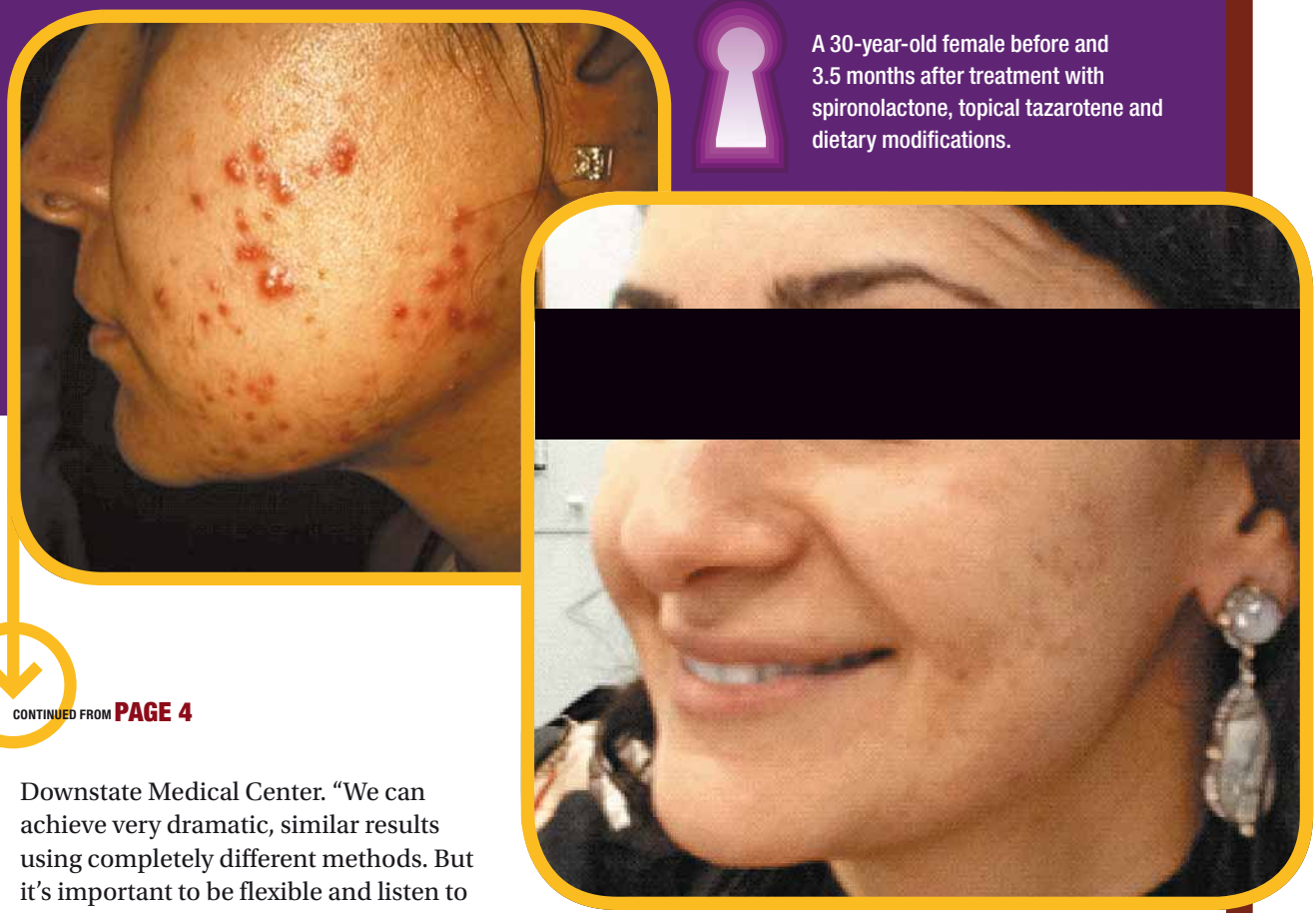
The proportion of subjects who experienced decreases in hemoglobin ≥1 g/dL was similar between **ACZONE**® Gel, 5% and vehicle treatment (8 of 58 subjects had such decreases during **ACZONE**® treatment compared to 7 of 56 subjects during vehicle treatment among subjects with at least one on-treatment hemoglobin assessment). Subgroups based on gender, race, or G6PD enzyme activity did not display any differences in laboratory results from the overall study group. There was no evidence of clinically significant hemolytic anemia in this study. Some of these subjects developed laboratory changes suggestive of mild hemolysis.

OVERDOSAGE

ACZONE® Gel, 5%, is not for oral use. If oral ingestion occurs, medical advice should be sought.

Rx ONLY

U.S. Patents 5,863,560; 6,060,085; and 6,620,435



A 30-year-old female before and 3.5 months after treatment with spironolactone, topical tazarotene and dietary modifications.

CLINICAL PHOTOS COURTESY OF WHITNEY P. BOWE, M.D.

CONTINUED FROM PAGE 4

Downstate Medical Center. "We can achieve very dramatic, similar results using completely different methods. But it's important to be flexible and listen to your patient's needs."

One case that illustrates this point involved a 27-year-old female patient who experienced severe acne since college. She presented with inflammatory papules and multiple cysts, according to Dr. Bowe, who spoke at the annual meeting of the American Academy of Dermatology.

"Her acne was severely affecting her quality of life," she says. "Specifically, she said that it was putting a heavy strain on her ability to get close to her boyfriend."

Additionally, the patient had a very specific goal: to look and feel better within one month, so she could attend New Year's Eve festivities with her boyfriend.

Clinically, Dr. Bowe says, "It's very challenging to have a dramatic impact on acne within one month." She told her patient she could flatten bumpy lesions to where they could be effectively covered with makeup, but she couldn't make it go away in one month.

"We must tailor our treatment recommendations based on the patient's acceptance of certain interventions, as well as their timeline."

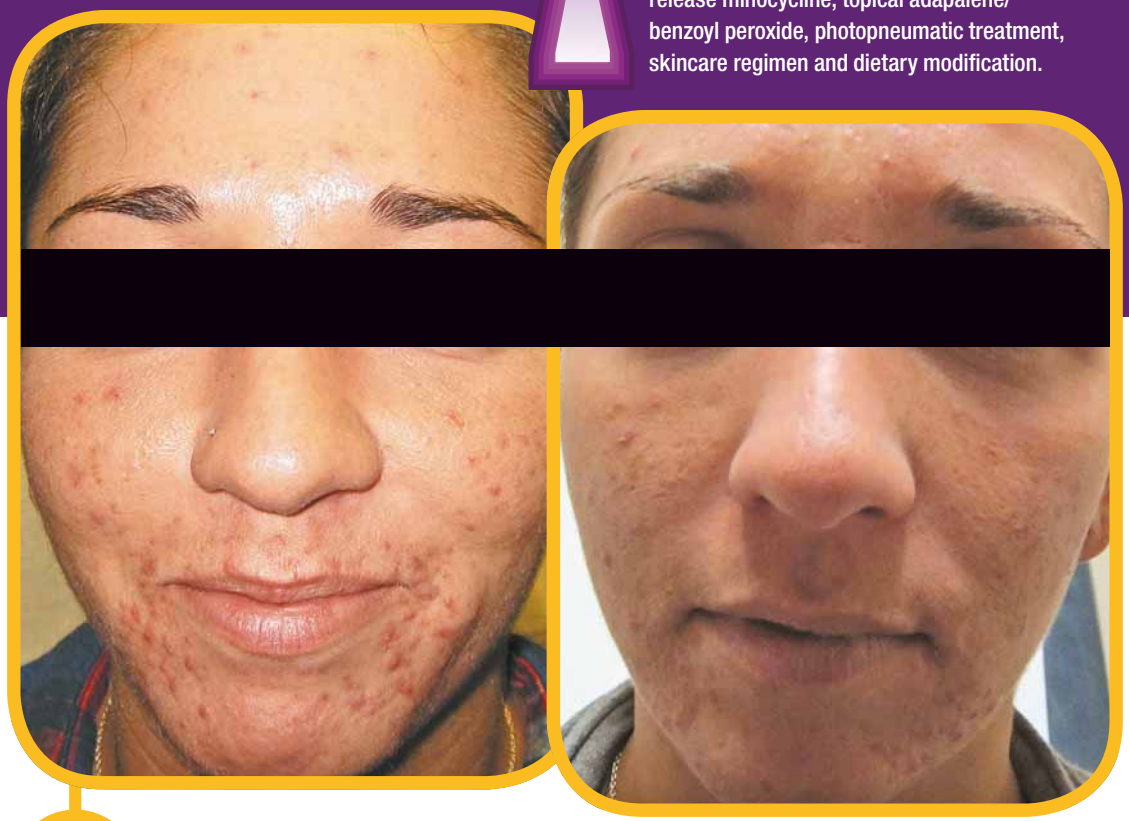
Whitney P. Bowe, M.D.
New York

Although the patient's acne affected her upper face, chest and back, it appeared most prominently on her chin and jawline. This suggested to Dr. Bowe that the patient might respond well to a hormonal intervention such as spironolactone. However, the patient rejected this treatment because she was already taking an oral contraceptive and didn't like the idea of adding another medication that could affect her hormones.

CONTINUED ON PAGE 8

Instead, "I put her on a combina-

ACNE



A 27-year-old female before and after one month of treatment including extended-release minocycline, topical adapalene/benzoyl peroxide, photopneumatic treatment, skincare regimen and dietary modification.

CLINICAL PHOTOS COURTESY OF WHITNEY P. BOWE, M.D.

CONTINUED FROM PAGE 7

tion of an extended-release minocycline tablet at 1 mg/kg dosing, and a topical formulation that combined adapalene and benzoyl peroxide," Dr. Bowe says. Initially the patient applied the topical medication every other night. After 10 days, the patient switched to every night because she was not experiencing dryness or irritation.

"To speed up the resolution of her acne, I added photopneumatic treatments," performed once weekly for four weeks with the Acleara Acne Clearing System (Palomar). "It's a non-painful treatment that involves broad-spectrum light and a vacuum apparatus that sucks out the contents of the pore and physically breaks up the biofilm within the pore."

"Soy is a natural brightener that can even out skin tone and texture."

Whitney P. Bowe, M.D.
New York

Additionally, Dr. Bowe says, the combination of red and blue light targets porphyrins naturally present in *Propionibacterium acnes* (without using a photosensitizer such as aminolevulinic acid), and has been shown to decrease the release of inflammatory cytokines in the skin.

SKINCARE REGIMENS

Simultaneously, Dr. Bowe recommended

CONTINUED ON PAGE 11

The #1 PRESCRIBED,
BRANDED TOPICAL ACNE AGENT IN THE WORLD IS...[1]

NOW THE **ONLY** TOPICAL ACNE AGENT **APPROVED FOR PATIENTS AS YOUNG AS 9 YEARS OF AGE!**

Important Safety Information

Indication: EPIDUO® Gel is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.
Adverse Events: In controlled clinical studies, the most commonly reported adverse events (≥1%) in patients treated with EPIDUO® Gel were dry skin, contact dermatitis, application site burning, application site irritation and skin irritation.
Warnings/Precautions: Patients taking EPIDUO® Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO® Gel and may necessitate discontinuation.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of full Prescribing Information on next page.

www.epiduo.com/hcp

IMPORTANT INFORMATION ABOUT

EPIDUO® GEL

(adapalene and benzoyl peroxide) Gel, 0.1% / 2.5%

BRIEF SUMMARY

This summary contains important information about EPIDUO (EP-E-Do-Oh) gel. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using EPIDUO gel. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about EPIDUO gel. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS EPIDUO GEL?

EPIDUO gel is a prescription medicine for skin use only (topical) used to treat acne vulgaris in people 9 years of age or older. Acne vulgaris is a condition in which the skin has blackheads, whiteheads, and pimples.

WHO IS EPIDUO GEL FOR?

EPIDUO gel is for use in people 9 years of age and older. It is not known if EPIDUO gel is safe and effective for children younger than 9 years old.

Do not use EPIDUO gel for a condition for which it was not prescribed. Do not give EPIDUO gel to other people, even if they have the same symptoms you have. It may harm them.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING EPIDUO GEL?

Before you use EPIDUO gel, tell your doctor if you:

- have other skin problems, including cuts or sunburn.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if EPIDUO gel can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use EPIDUO gel.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

- Especially tell your doctor if you use any other medicine for acne. Using EPIDUO gel with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.
- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

WHAT SHOULD I AVOID WHILE USING EPIDUO GEL?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO gel can make your skin sensitive to sun and the light from tanning beds and sunlamps. You should wear sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO gel if you have to be in the sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying EPIDUO gel to cuts, abrasions and sunburned skin.
- You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol.
- You should avoid the use of "waxing" as a hair removal method on skin treated with EPIDUO gel.
- EPIDUO gel may bleach your clothes or hair. Allow EPIDUO gel to dry completely before dressing to prevent bleaching of your clothes.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF EPIDUO GEL?

The most commonly reported side effects when using EPIDUO gel include erythema, scaling, dryness, application site irritation, stinging and burning.

Depending upon the severity of these side effects, patients should be instructed to use a moisturizer, reduce the frequency of the application of EPIDUO gel, or discontinue use.

Tell your doctor right away if these side effects continue for longer than 4 weeks or get worse, you may have to stop using EPIDUO gel. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of EPIDUO gel. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

HOW SHOULD I USE EPIDUO GEL?

- Use EPIDUO gel exactly as your doctor tells you to use it. EPIDUO gel is for skin use only. Do not use EPIDUO gel in or on your mouth, eyes, or vagina.
- Apply EPIDUO gel 1 time a day.
- Do not use more EPIDUO gel than you need to cover the treatment area. Using too much EPIDUO gel or using it more than 1 time a day may increase your chance of skin irritation.

APPLYING EPIDUO GEL:

- Wash the area where the gel will be applied with a mild cleanser and pat dry.
- EPIDUO gel comes in a tube and a pump. If you have been prescribed the:
  - Tube: Squeeze a small amount (about the size of a pea) of EPIDUO gel onto your fingertips and spread a thin layer over the affected area.
  - Pump: Depress the pump to dispense a small amount (about the size of a pea) of EPIDUO gel and spread a thin layer over the affected area.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT EPIDUO GEL?

- Talk to your doctor or pharmacist
- Go to **www.epiduo.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: February 2013

Reference: 1. IMS Health - Monthly Midas Database, all countries selected - Topical Anti Acne Market - November 2012 MAT, retail RX market - at sales manufacturer local currency dollar value - Copyright IMS Health or its affiliates. All rights reserved.

Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
EPI-984R Printed in USA 02/13

www.epiduo.com/hcp

GALDERMA
Committed to the future of dermatology

Epiduo®
(adapalene and benzoyl peroxide) Gel 0.1% / 2.5%

VOICE OF THE DERMATOLOGIST

It's important to **be flexible and listen** to your patient's needs.

Whitney P. Bowe, M.D., New York

page 7

CONTINUED FROM PAGE 8

a daily skincare regimen that met the patient's desire for simplicity while also calming and moisturizing her skin to help it withstand aggressive treatment. Specifically, "I gave her a morning moisturizer with a sun protection factor of 30 and a soy complex. The soy is a natural brightener that can even out skin tone and texture." The patient also used gentle cleansers and an evening moisturizer containing ceramides.

Finally, Dr. Bowe recommended that the patient minimize her consumption of foods with a high glycemic index, such as white bread. "She was also drinking a lot of skim milk, which we replaced with almond milk, because skim milk has been known to exacerbate acne."

Based on other evidence, Dr. Bowe added a daily probiotic supplement and fish oil (its high omega-3 content provides anti-inflammatory action). The patient also maximized her antioxidant ingestion by adding more deeply colored fruits and vegetables.

"One month later, the active acne had almost completely resolved. She was left with just postinflammatory erythematous macules that she could easily cover up with a light foundation. She was ecstatic, and she has remained clear since then," Dr. Bowe says.

The patient discontinued the oral antibiotics after three months, but continues using the topical medication and dietary and skincare regimens, she says.

In contrast, Dr. Bowe treated a young woman who presented with similar symptoms but much different expectations using a different approach. "She was open to trying spironolactone, and she was not in such a rush to achieve results." In addition to the spironolactone, Dr. Bowe prescribed a topical retinoid (tazarotene) and implemented the dietary modifications above. "Her skin was perfectly clear in 3.5 months." **DT**

Disclosure: Dr. Bowe has been a consultant for Galderma and Johnson & Johnson Consumer Products.

ACNE

Guidelines for managing acne in children promote more consistent care

PEDIATRIC APPROACH

By John Jesitus
Senior Staff Correspondent

With acne presenting in increasingly younger patients, new guidelines developed by the American Acne and Rosacea Society (AARS) promote more consistent care for pediatric patients, according to an expert.

"Acne is increasingly common in preadolescents, as well as adolescents," says Lawrence F. Eichenfield, M.D., chief of pediatric and adolescent dermatology at Rady Children's Hospital and professor of pediatrics and medicine (dermatology) at the University of California, San Diego. He spoke at the annual meeting of the American Academy of Dermatology.


Dr. Eichenfield

Simultaneously, "We know that there is a younger onset of puberty in both girls and boys. This means that a younger set of patients can present for evaluation of their acne."

Moreover, "We know that there are tremendous variations — especially among pediatricians, primary care practitioners and dermatologists — in how people manage acne." Such variations involve the appropriate use of retinoids in managing all types of acne, and of systemic antibiotics in moderate-to-severe acne, he says.

GUIDELINES BY AGE

Fortunately, Dr. Eichenfield says, "We believe that the guidelines for pediatric acne will increase health practitioners' knowledge about pediatric acne and improve care for these patients (Eichenfield LF, Krakowski AC, Piggott C, et al. *Pediatrics*. 2013;131 Suppl 3:S163-S186)." The American Academy of Pediatrics also endorses the guidelines.

CONTINUED ON PAGE 15

CONTINUED FROM PAGE 12

Central to the guidelines is classifying acne by age. In this regard, the lesions of neonatal acne (ages 0 to 6 weeks) are more acneiform than true acne, Dr. Eichenfield says.

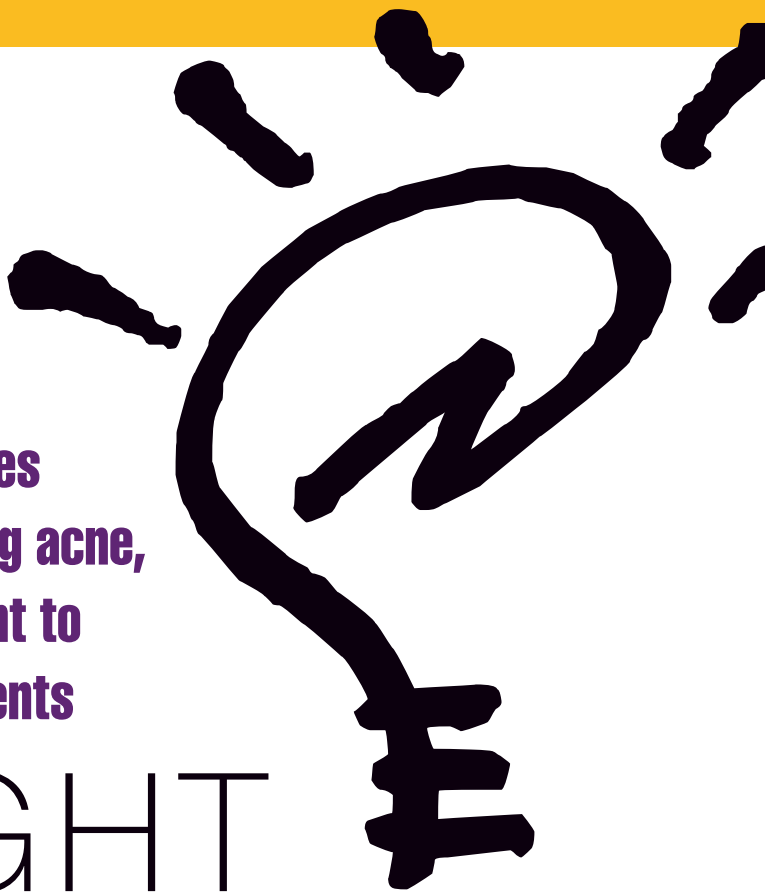
"Many pustular eruptions have traditionally been called neonatal acne, though they may not be true acne. One such variation is neonatal cephalic pustulosis, which has been associated with *Malassezia species* (*M. sympodialis* and *M. globosa*)."

Infantile acne can present from a few months to one year of age. "It's true acne, with comedones usually present. In addition, patients can have inflammatory papules, pustules, nodules and cyst-like lesions."

Mid-childhood acne (ages 1 to less than 7 years) is the most worrisome form of pediatric acne, Dr. Eichenfield says. Fortunately, "It's very uncommon in an otherwise well child. Sebaceous glands usually are not active, or relatively inactive, in this age group." However, he adds, the presence of acne in mid-childhood should warrant a workup for an underlying systemic cause (the guidelines also suggest a referral to a pediatric endocrinologist). Systemic causes can include premature adrenarche, Cushing's syndrome, congenital adrenal hyperplasia, gonadal adrenal tumors or precocious puberty, he says.

CONTINUED ON PAGE 21

ACNE



Laser, light devices useful for clearing acne, scars recalcitrant to standard treatments

BRIGHT IDEA

By Ilya Petrou, M.D.
Senior Staff Correspondent

While topical and oral therapies remain the gold standard approach for treating acne, laser and light sources are effective for acne lesions and scarring, and can be particularly useful in cases recalcitrant to standard therapeutic approaches, an expert says.

Getty Images/

"Laser and light sources have come of age and are proving to be very useful in the treatment of numerous medical and cosmetic conditions in dermatology including acne and acne scarring," says


Dr. Katsambas

Andreas D. Katsambas, M.D., professor, department of dermatology, Andreas Sygros Hospital for Skin and Venereal Diseases, Athens, Greece. Dr. Katsambas spoke at the Dubai World Dermatology & Laser Conference & Exhibition in India.

GENTLER TREATMENT

Ablative, nonablative and fractional laser sources can be used to effectively treat acne scars, but of these modalities, Dr. Katsambas says nonablative fractional laser sources are often the preferred choice. Compared to ablative laser sources, nonablative and fractional lasers are typically associated with much less downtime, he says, and are more tolerable for the patient.

"There is a very mild, cosmetically acceptable erythema following nonablative fractional laser treatment and after five to six treatment sessions, most patients will see about 70-80 percent improvement in their lesions," Dr. Katsambas says.

While ablative laser treatments will usually have a more dramatic impact and are ultimately more effective in improving the cosmesis of acne scars, patients can expect as much as two weeks of downtime with ablative lasers, while the downtime typically associated with nonablative fractional lasers can be as little as one to two days, he says.

Propionibacterium acnes **is one of the major causes of acne and produces different porphyrin types, such as coproporphyrin and protoporphyrin.**

AVOIDING PIH

Postinflammatory hyperpigmentation (PIH) is a potential side effect following laser therapy, which can be more of an issue in patients with darker Fitzpatrick skin types. According to Dr. Katsambas, the risk of PIH can be as high as 90 percent after ablative laser therapy, which is in stark contrast to the only 13 percent risk in patients following nonablative fractional laser treatment. Although PIH is typically a transient side effect, Dr. Katsambas says it can last for as much as six months in patients treated with ablative lasers, compared to a maximum of one week following nonablative fractional laser treatment.

PIH risk can be up to 90 PERCENT after ablative laser therapy

"This difference in downtime can be crucial to the patient who has a very busy work and social life and cannot afford weeks or months of persistent erythema and the other side effects typically associated with the more intense ablative laser therapy," Dr. Katsambas says.

Depending on the severity of acne scarring, Dr. Katsambas will typically perform four to six nonablative fractional laser treatments spaced one month apart. Dr. Katsambas also advises his patients to avoid sun exposure at least two weeks following acne scar laser treatments. He prefers to perform these treatments in the winter months in order to help minimize

CONTINUED ON PAGE 18

ACNE

VOICE OF THE DERMATOLOGIST

"Laser and light sources have come of age and **are proving to be very useful** in the treatment of numerous medical and cosmetic conditions."

Andreas D. Katsambas, M.D., Athens, Greece **page 17**

CONTINUED FROM **PAGE 17**

the overall risk of PIH.

Propionibacterium acnes (P. acnes) is one of the major causes of acne and produces different porphyrin types such as coproporphyrin and protoporphyrin. According to Dr. Katsambas, light therapy using blue or red light as well as photodynamic therapy (PDT) are ideally suited for the treatment of acne because the porphyrins synthesized by P. acnes in the sebaceous follicles act as photosensitizers and attract the therapeutic light.

COMBINATION TREATMENTS

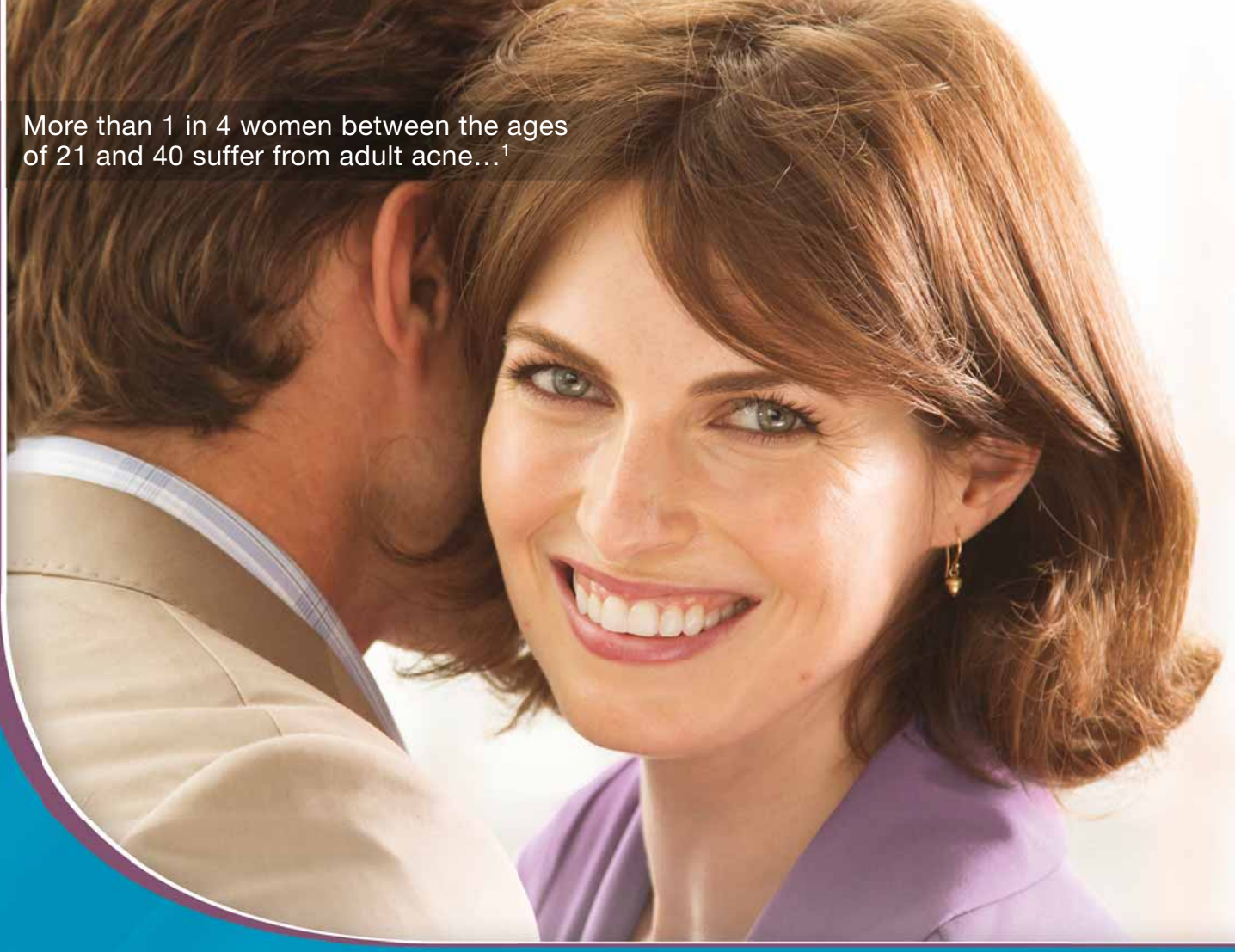
The choice of blue or red light or PDT to treat acne depends on several factors, including the type and severity of the acne lesions the patient has, the age of the patient and the downtime the patient is willing to endure.

"Photodynamic therapy can achieve excellent outcomes; however, the approach is often associated with pain, and the subsequent inflammation following treatment could last for a week or longer," Dr. Katsambas says. "As a result, some patients may shy away from PDT and choose other treatments such as blue or red light, which may be less effective, but are much better tolerated by patients and have minimal downtime."

Dr. Katsambas says he still uses topical and oral therapies in his acne patients, and only if there are contraindications to these will he move ahead with laser and light sources. Due to the unsettling increase in antibiotic resistances seen in acne, Dr. Katsambas prefers to refrain from prescribing oral and topical antibiotics in his acne patients. Except for isotretinoin, he says he will often combine laser and light therapy with other acne treatments including contraceptives, retinoids, benzoyl peroxide or azelaic acid.

"We are very fortunate to have an ever-expanding armamentarium to treat every form of acne of all severities. If for one or another reason a therapy proves ineffective, we can easily choose another proven approach and often achieve good to excellent clinical outcomes in our patients," Dr. Katsambas says. **DT**

Disclosure: Dr. Katsambas reports no relevant financial interests.



REAL WOMEN
get adult acne[1]

REAL NEED
because acne and skin change over time[1,2]

REAL REASON
to prescribe Differin® (adapalene) Gel, 0.3%

Effectively clears adult inflammatory acne with a tolerability profile that addresses the needs of her changing skin[3,4*†]

*A phase 3, 12-week, multicenter, randomized, active- and vehicle-controlled, double-blind, parallel-group clinical study of patients 12 years or older with acne vulgaris (N=653).

†Signs and symptoms of skin irritation were mostly mild or moderate in severity. Erythema, scaling, dryness, and stinging/burning were transient in duration, peaking during the first weeks of treatment and decreasing over time.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

Differin® 0.3 (ADAPALENE) GEL, 0.3%

www.differin.com/hcp

RESULTS REAL WOMEN WANT

IMPORTANT INFORMATION ABOUT
DIFFERIN® Gel
(adapalene) Gel, 0.3%

BRIEF SUMMARY

This summary contains important information about DIFFERIN [Dif-er-in] Gel, 0.3%. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using DIFFERIN Gel, 0.3%. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about DIFFERIN Gel, 0.3%. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS DIFFERIN GEL, 0.3%?

DIFFERIN (adapalene) Gel, 0.3% is a prescription medicine known as a retinoid and is indicated for the topical (skin use only) treatment of acne vulgaris in people 12 years of age and older.

WHO IS DIFFERIN GEL, 0.3% FOR?

DIFFERIN Gel, 0.3% is for patients age 12 and older.

You should not use DIFFERIN Gel, 0.3% if you are allergic to adapalene or any of the ingredients in DIFFERIN Gel, 0.3%. For a complete listing of ingredients, please see the full prescribing information.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING DIFFERIN GEL, 0.3%?

Tell your doctor about all your health conditions, especially if you

- have other skin problems, including cuts or sunburn.
- have any other medical conditions.
- are pregnant or planning to become pregnant. It is not known if DIFFERIN Gel, 0.3% can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if DIFFERIN Gel, 0.3% passes into your breast milk and if it can harm your baby.
- are using any other prescription or non-prescription medications, including vitamins and herbal supplements.
- Especially tell your doctor if you are using any other medication for acne. Using DIFFERIN Gel, 0.3% with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.

WHAT SHOULD I AVOID WHILE USING DIFFERIN GEL, 0.3%?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. DIFFERIN Gel, 0.3% can make your skin sensitive to sun and the light from tanning beds and sunlamps. Use sunscreen and wear a hat and clothes that cover the areas treated by DIFFERIN Gel, 0.3% if you have to be in sunlight.
- Weather extremes, such as cold or wind, may irritate the skin of patients using DIFFERIN Gel, 0.3%.
- Products containing alpha hydroxy or glycolic acids should be avoided.
- This medication should not be applied to cuts, abrasions, eczematous or sunburned skin.
- Do not wax the treatment area while using DIFFERIN Gel, 0.3%. It could damage the treated skin.
- Limit use of the following while using DIFFERIN Gel, 0.3% as they may cause irritation:
    - harsh soaps
    - astringents
    - cosmetics that have strong skin drying effects
    - products with high concentrations of alcohol
    - preparations containing sulphur, resorcinol or salicylic acid
    - products containing alpha hydroxy or glycolic acid.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF DIFFERIN GEL, 0.3%?

The most common side effects associated with use of DIFFERIN Gel, 0.3% are skin pain, skin peeling, and sunburn.

Other local skin reactions that are most likely to happen during the first 4 weeks of treatment and lessen with continued use of DIFFERIN Gel, 0.3% include dryness, redness, burning/stinging, and scaling.

Moisturizers may be used if necessary.

If you experience any of the following symptoms of a potential allergic reaction while taking DIFFERIN Gel, 0.3%, you should stop using the medication and consult a doctor.

- skin rash, itching or hives
- trouble breathing or chest pain
- swelling of your face, eyes, lips, tongue or throat

These are not all of the possible side effects of DIFFERIN Gel, 0.3%. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

HOW SHOULD I USE DIFFERIN GEL, 0.3%?

- Use DIFFERIN Gel, 0.3% exactly as prescribed by your doctor.
- Unless you have been instructed otherwise, apply a thin film of DIFFERIN Gel, 0.3% once daily to entire face or affected area(s) after washing gently with a non-medicated soap and patting the area dry.
- DIFFERIN Gel, 0.3% is for skin use only. It is not for use in or on your mouth, eyes or vagina.
- Do not use more than the recommended amount daily as this will not produce faster results, but may increase irritation.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT DIFFERIN GEL, 0.3%?

- Talk to your doctor or pharmacist
- Go to **www.differin.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: March 2012
P51958-0-BS

GALDERMA
Committed to the future of dermatology

Differin® 0.3
(ADAPALENE) GEL, 0.3%

References: 1. Perkins AC, Maglione J, Hillebrand GG, Miyamoto K, Kimball AB. Acne vulgaris in women: prevalence across the life span. *J Womens Health.* 2012;21(2):223-230. **2.** MedlinePlus®. Aging changes in skin. http://www.nlm.nih.gov/medlineplus/ency/article/004014.htm. Accessed December 4, 2012. **3.** Thiboutot D, Pariser DM, Egan N, et al; Adapalene Study Group. Adapalene gel 0.3% for the treatment of acne vulgaris: a multicenter, randomized, double-blind, controlled, phase III trial. *J Am Acad Dermatol.* 2006;54(2):242-250. **4.** Adult acne female subgroup analysis of phase 2 and 3 clinical studies, manuscript in preparation, 2012: Data on file, Galderma Laboratories, L.P.

Galderma Laboratories, L.P.
14501 N. Freeway
Fort Worth, TX 76177
DIFF-295 Printed in USA 11/12

www.differin.com/hcp

CONTINUED FROM PAGE 15

Preadolescent acne (ages 7 to 12 years) is much more common, and generally not associated with underlying endocrinopathy, Dr. Eichenfield says.

"It often presents with early comedones of the forehead and midface," he says. "It's been shown that early significant acne can correlate with advanced pubertal maturation and signal a higher risk for severe acne over time."

ADDITIONAL FACTORS

Acne type, extent and severity also drive treatment choices. In the former area, the guidelines specify that pediatric acne can be comedonal, mixed (comedonal/inflammatory) or nodular/cystic. As for severity, the guidelines recommend considering the presence of acne scarring and the impact of acne on a child's psychological health and development.

Addressing each of the foregoing parameters, the guidelines include an algorithm that covers initial acne treatment, along with additional strategies to consider if patients don't respond adequately to these options.

"For instance, for mild acne (comedonal or inflammatory/mixed), the general approach is a topical regimen. The initial treatment can be benzoyl peroxide, or a topical retinoid, as monotherapy," Dr. Eichenfield says. "Alternatively, one can prescribe topical combination therapy, which can include benzoyl peroxide, antibiotics, retinoids or combination products." If initial treatment fails, he adds, dermatologists already prescribing topical retinoids can consider changing the retinoid type, concentration and/or formulation.

For moderate acne, "Initial treatment can include topical combination therapies, including a retinoid and an antimicrobial. Alternatively, one can initiate therapy with an oral antibiotic and a topical retinoid, with benzoyl peroxide advised to minimize the emergence of bacterial resistance."

"Oral antibiotics are appropriate for moderate-to-severe inflammatory acne at any age, as long as one avoids the cycline-based products in patients under age 8."

Lawrence Eichenfield, M.D.
San Diego

Additionally, Dr. Eichenfield says that evidence-based guidelines offer specific recommendations by therapeutic class.

ANTIBIOTIC CAUTION

"Topical antibiotics (clindamycin, erythromycin) are not recommended as monotherapy. And if they are to be used for more than a few weeks, topical benzoyl peroxide should be added, or utilized in combination products," he says.

Likewise, he adds, dermatologists can prescribe fixed-dose combination topical products for all types and severities of acne. In this regard, a recent study of a benzoyl peroxide-adapalene combination (Eichenfield LF, Herbert AA, Lucky AW, et al. *J Am Acad Dermatol.* 2013; Abstract P6243. 68(4): Suppl 1, AB19. In press, *J Drugs Dermatol.*) resulted in a U.S. Food and Drug Administration indication for use in children as young as age 9.

Somewhat similarly, "Oral antibiotics are appropriate for moderate-to-severe inflammatory acne at any age, as long as one avoids the cycline-based products in patients under age 8," he says, because these drugs can permanently stain teeth. The guidelines also recommend isotretinoin for severe acne scarring or refractory acne in adolescents.

"We may utilize it in younger patients as well — with extensive, appropriate counseling regarding potential side effects and the need to avoid pregnancy," he says. **DT**

Disclosures: Dr. Eichenfield co-chaired the AARS guideline committee with Diane Thiboutot, M.D. His adapalene/benzoyl peroxide study was supported by Galderma.

ACNE

Research stat

Tazarotene foam reduced acne severity

Journal of Drugs in Dermatology
APRIL 2013

A TAZAROTENE FOAM 0.1 PERCENT significantly reduced the severity of acne lesions after 12 weeks.

Researchers at Wake Forest University Health Sciences, Winston-Salem, N.C., and colleagues conducted parallel randomized, double-blind, vehicle-controlled, phase 3 studies at 39 centers in the United States and Canada to assess the clinical efficacy, safety and tolerability of tazarotene foam, 0.1 percent compared with vehicle foam.

The studies enrolled nearly 1,500 patients ages 12 to 45 years old with moderate to severe acne vulgaris, who were randomized to receive tazarotene foam 0.1 percent or a vehicle foam once daily for 12 weeks. Researchers found that the group treated with tazarotene foam had a greater decrease in lesion count ,a higher number of patients with a ≥ 2-grade improvement in the ISGA score, and a larger number of patients with ISGA score of) or 1 compared with vehicle treatment (P<.001).

Application-site skin irritation and drying was reported by > 5 percent of patients treated with tazarotene in both studies. Tolerability was monitored throughout the study and shown to have a safe and acceptable profile. Tolerability and efficacy were not directly compared to other formulations, the researchers noted.

http://jddonline.com/articles/dermatology/S1545961613P0438X

Zinc may act against acne vulgaris

Journal of Drugs in Dermatology
MAY 2013

ZINC MAY HAVE ANTIBACTERIAL and anti-inflammatory effects that can decrease sebum production and reduce the appearance of acne vulgaris.

Using keywords, such as "acne," "zinc," "topical," and "skin", researchers at Galderma Laboratories conducted a literature review of articles published in English over the past 30 years. Articles were rated for quality and assigned scores based on Strength of Recommendation Taxonomy (SORT) criteria. The body of evidence on oral or topical zinc for the treatment of acne was given a SORT strength recommendation of B, meaning there was inconsistent or limited-quality patient-oriented evidence. However, the evidence suggested that zinc has antibacterial and anti-inflammatory effects that may decrease sebum production, according to the abstract.

http://jddonline.com/articles/dermatology/S1545961613P0542X

Salicylic acid peel effective treatment for moderate acne

Dermatologic Surgery APRIL 2013

A FACE PEEL containing 30 percent salicylic acid, triethyl citrate, and ethyl linoleate may be an effective treatment for patients with moderate acne.

Researchers at Sant'Orsola-Malpighi Hospital, University of Bologna, Italy, conducted a prospective, observational, multicenter, open-label, postmarketing, phase 4 study in which they enrolled 53 patients.

The treatment peel contained 30 percent salicylic acid, triethyl citrate, and ethyl linoleate. It was combined with a home therapy system, which included triethyl citrate, ethyl linoleate, and salicylic acid 0.5 percent cream and lotion.

Researchers compared Global Acne Grading System (GAGS) scores and total lesion counts for each patient 15 days prior to their first peel, approximately 10 days after four peels, and 20 days after the end of the study.

The average GAGS score fell 49 percent between T–15 and

T50 ($p < .001$), the researchers found. The treatment was well-tolerated, as none of the patients withdrew due to adverse events, according to the abstract.

http://onlinelibrary.wiley.com/doi/10.1111/dsu.12215/abstract

PDL recommended for acne vulgaris

Journal of the American Academy of Dermatology **MAY 2013**

RESEARCHERS RECOMMEND PULSED DYE LASER (PDL) treatment for acne vulgaris.

Researchers at Sant'Orsola-Malpighi Hospital, University of Bologna, Italy, conducted a literature search for searched for all publications reporting on PDL treatment for an inflammatory skin disease from January 1992 to August 2011.

Researchers found 52 articles in which PDL was used to treat inflammatory skin diseases such as acne vulgaris, psoriasis, lupus erythematodes, granuloma faciale, sarcoidosis, eczematous lesions, papulopustular rosacea, lichen sclerosis, granuloma annulare, Jessner lymphocytic infiltration of the skin, and reticular erythematous mucinosis. The researchers evaluated and described the efficacy of treatment on each of these conditions.

For localized plaque psoriasis and acne vulgaris, the authors say PDL treatment can be recommended as an effective and safe treatment (recommendation grade B).

http://www.jaad.org/article/S0190-9622(13)00310-1/abstract

Continuous low-dose isotretinoin superior for acne vulgaris

International Journal of Dermatology **MAY 2013**

A CONTINUOUS LOW-DOSE isotretinoin therapy is superior to intermittent therapy for the treatment of moderate acne vulgaris.

Researchers from the Ankara Training and Research Hospital, Ankara, Turkey, divided 60 patients into two groups to compare intermittent with continuous low-dose isotretinoin therapy. The researchers followed each patient for at least six months following therapy.

Researchers reported no statistically significant differences in improvement rates between groups; however, mean acne score reduction rates favored the continuous low-dose patient group. No relapses occurred in the low-dose group, while three occurred in the intermittent group. There were no side effects reported in either group, the researchers noted.

Although both treatments are well tolerated and effective, a continuous low-dose therapy was slightly more superior, the researchers concluded.

http://onlinelibrary.wiley.com/doi/10.1111/j.1365-4632.2012.05853.x/abstract

PRP, erbium fractional laser therapy effective for acne, scars

Molecular Medicine Reports **MAY 2013**

A COMBINED TREATMENT including platelet-rich plasma and erbium fractional laser therapy appears to be an effective and safe approach for treating acne and acne scars.

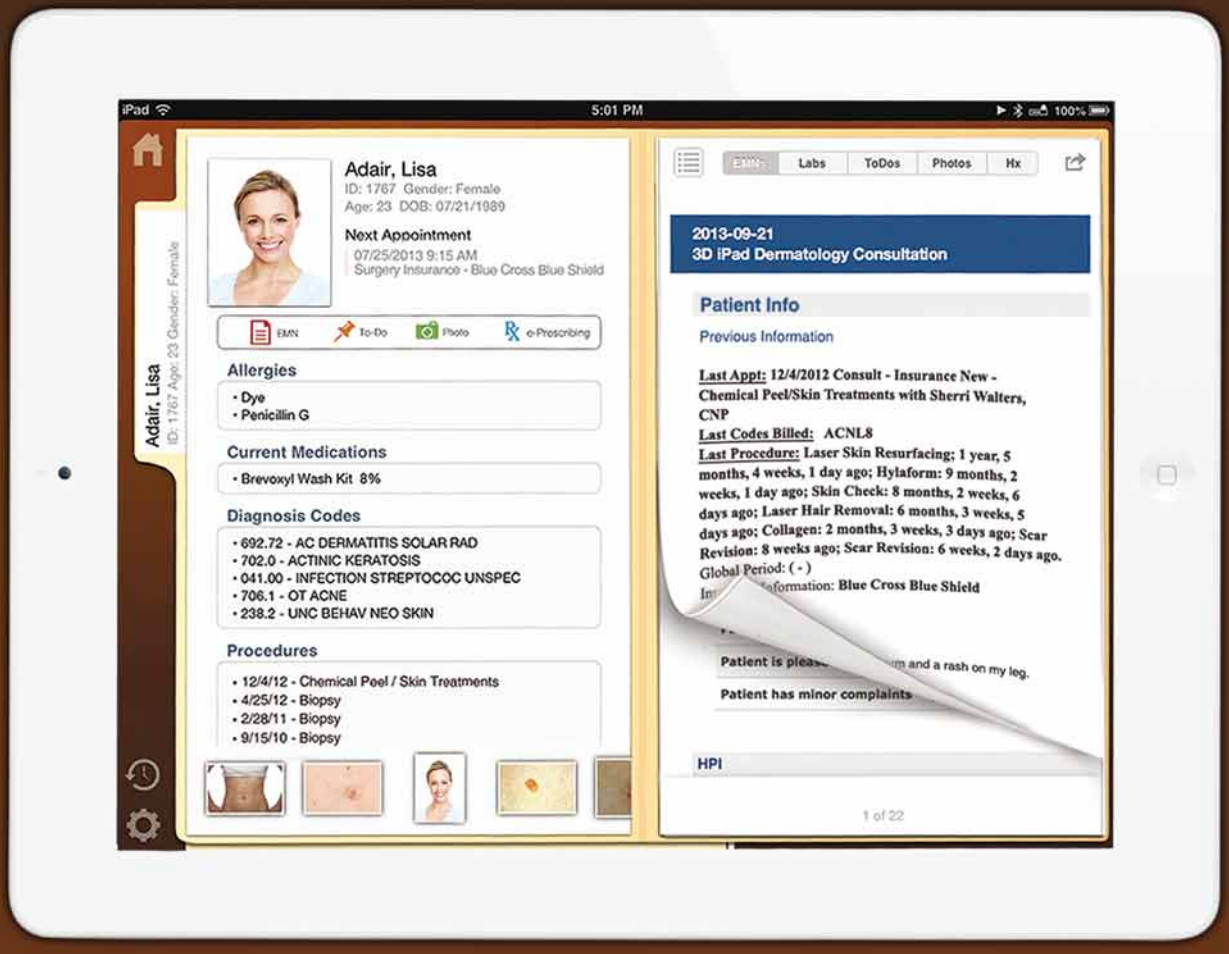
Researchers from Guangzhou General Hospital of Guangzhou Military Command, Guangzhou, Guangdong, P.R. China evaluated 16 patients with facial acne scars and 6 patients with acne scars and acne.

PRP was applied to each patient's face following laser treatment. Before and after photos were evaluated on a five-point scale. After three treatments, more than 90 percent of the patients showed an improvement of >50 percent, 91 percent of the patients reported satisfaction; erythema was mild and lasted less than 3 days; no acne inflammation was observed after treatment, the researchers found.

http://www.spandidos-publications.com/10.3892/mmr.2013.1455

Your Charts, Customized Your Way

NexTech INTEGRATED EMR & PM solutions are designed to match the workflow of each Dermatologist. Our patented native iPad® app provides the look and feel of paper charts in the palm of your hand.



Fully Customizable
Easy - Intuitive Use
Fast Implementation

EMR & PM in a Single Database
Windows and /or iPad®
Subscription or Perpetual License®

Software Designed for Dermatology

ONC-ATCB CERTIFIED Supporting Meaningful Use 2011-2012 by CCHIT Complete EHR Eligible Provider

NexTech Practice 2013 v10.3

CCHIT CERTIFIED 2011 Ambulatory EHR +Dermatology

NexTech® EMR & PM

www.nextech.com • websales@nextech.com • (866) 857-7809

NexTech Practice 2013 v10.3 CC-1112-998990-2 www.nextech.com/meaningful-use.aspx