Top 4 curation Apps

"This app **condenses** information into a **CliffsNotes-like set-up.**"

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Dermatology Times®

Clinical Analysis for Today's Skincare Specialists

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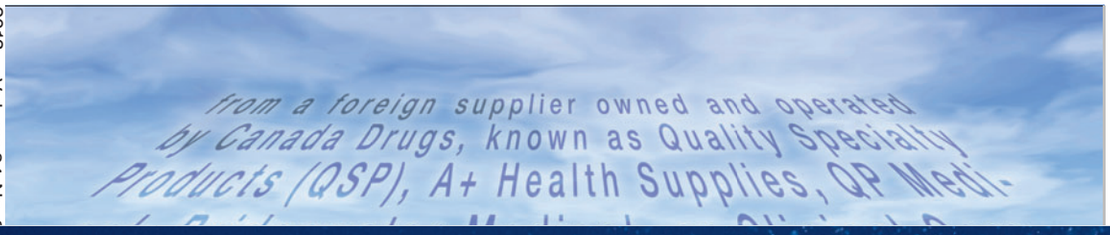
August 2013 / Vol. 34, No. 8 | twitter.com/DermTimesNow



Phony products not worth risk

DERMATOLOGYTIMES.COM/COUNTERFEITS

Dermatology Times presents the first discussion in a series on fillers and neuromodulators, which was

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.

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Revised: April 2013

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Dermatology Times®

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COMBATING COUNTERFEITS

HOW DERMS HELP KNOCK OUT MARKET IMITATORS

By Lisette Hilton | STAFF CORRESPONDENT

FOR DERMATOLOGISTS, battling the growing problem of drug counterfeiting requires wariness and common sense, says a Food and Drug Administration expert who spoke at Cosmetic Boot Camp, held recently in Aspen, Colo.

"Medical practitioners are very key players in combating counterfeits and making sure that the supply chain is safe for patients, and for practitioners," says Karen Rothschild, Esq., regulatory counsel with the FDA Center for Drug Evaluation and Research.

Over the past 18 months, the FDA has established the Office of Drug Security, Integrity and Recalls, which includes the Division of Supply Chain Integrity, where Ms. Rothschild works. As part of this effort, the agency sent informational letters to doctors and other medical practitioners who, according to FDA evidence, had purchased drugs from unlicensed suppliers — whether intentionally or unintentionally.

"We warned against the use of any drugs from unlicensed suppliers because they may be counterfeit," and urged practices not to use any of these drugs — and to share information that would help the FDA prosecute the unauthorized sellers.

COUNTERFEITS see page 33

Phony products not worth risk

DERMATOLOGYTIMES.COM/COUNTERFEITS

Dermatology Times presents the first discussion in a series on fillers and neuromodulators, which was conducted at the recent Vegas Cosmetic Surgery and Aesthetic Dermatology Meeting. Experts across the field discussed best practices for use and key issues surrounding product differences, challenges, patient care and consent, and adverse events. Our first part focuses on the growing counterfeit market, lessons learned and ethical practice pearls.

RISKY BUSINESS see page 26

COSMETIC DERMATOLOGY

DERMAL γδ T CELLS

A new player in the pathogenesis of psoriasis

By Ilya Petrou, M.D. | SENIOR STAFF CORRESPONDENT

RESEARCHERS have recently identified gamma delta T cells as having an important role in the pathogenesis of psoriasis. This breakthrough in the pathogenesis of the disease could have far-reaching implications in terms of more targeted therapies for psoriasis in the future.

GAMMA DELTA T CELLS see page 20

CLINICAL DERMATOLOGY

MORE *IN THIS ISSUE*

CUTANEOUS ONCOLOGY

BUSINESS OF DERMATOLOGY

ADVANSTAR MEDICAL COMMUNICATIONS GROUP

Dermatology Times® August 2013 Volume 34 No. 8 Leading News and Analysis for Today's Dermatologists DermatologyTimes.com

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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.

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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.

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SEE WHAT WE HAVE IN STORE FOR YOU THIS MONTH

RESOURCES IN DERMATOLOGY

Access resources that will aid in successful and efficient adoption of electronic health records systems and attest to meaningful use, stage 1.
dermatologytimes.com/EHRinvestments

Review a broad range of clinical, CME and digital information about conditions like psoriasis, rosacea and melanoma. Learn emerging treatment options to help patients reduce symptoms.
dermatologytimes.com/fragileskintherapies

Trending FROM July

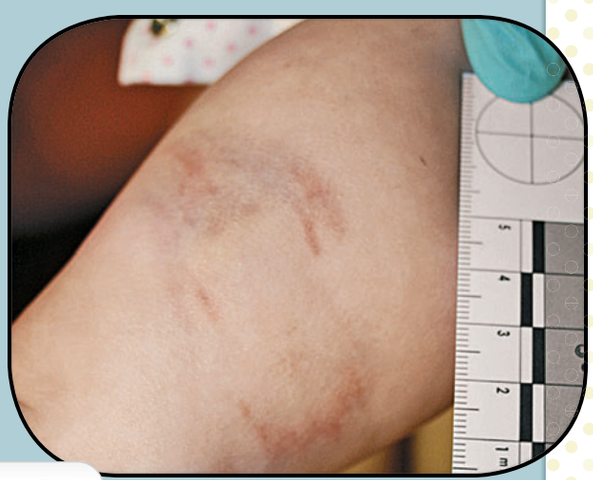
After four and a half years of sunscreen use, there was no detectable increase in skin aging observed in a group that used sun protection daily, investigators report.
dermatologytimes.com/dailysunscreen

Thyroid function assessment should be considered standard practice in patients with a personal or family history of autoimmune disease, as well as in patients with cutaneous symptoms suggestive of either hyper- or hypothyroid states, an expert says.
dermatologytimes.com/thyroid

Children between 7 months and 13 years of age and women ages 16 to 45 are the two groups most likely to present with perioral dermatitis. Paying close attention to rash morphology and location can aid in making an accurate diagnosis.
dermatologytimes.com/perioral

What's your diagnosis?

You are asked to evaluate a 4-month-old girl with multiple areas of purpura, including a distinctive bruise on the lateral aspect of the left thigh. The child's mother states that she noticed these lesions after picking up the infant from her biologic father, who was watching the child alone. No trauma history is reported. The child has been otherwise in good health, with no signs of infection.



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The Business of Dermatology

App helps doctors track Sunshine Act reports

The Open Payments app, released in time for implementation of the Physician Payments Sunshine Act, allows physicians to track real-time payments and other value transfers to drug and device manufacturers.

dermatologytimes.com/openpayments

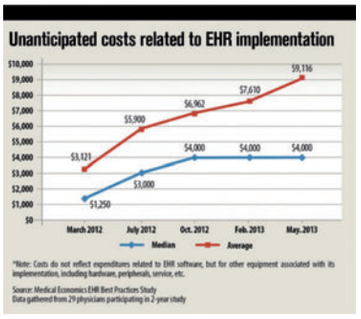
Experts examine ACA's impact on physicians

As the Oct. 1 open enrollment deadline nears for the Affordable Care Act's (ACA) health insurance exchanges, there are many unanswered questions about the ACA's impact on physician practices.

dermatologytimes.com/ACAimpact

An update on EHR best practices survey

A new wave of data from the two-year *Medical Economics* Best Practices Study that began in January 2012 shows that average out-of-pocket



expenditures related to EHR implementation has steadily risen from $3,121 in March 2012 to $9,116 in July 2013.

dermatologytimes.com/EHRstudy

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insight & opinion from our advisory board leaders

Patti Farris, M.D., is clinical associate professor at Tulane University and a partner at Old Metairie Dermatology in Metairie, La.

Descriptive or deceptive?

A critical look at the term 'cosmeceutical'

The term "cosmeceutical" was coined in 1984 by Albert Kligman, M.D., Ph.D., to describe an emerging category of skincare products. Dr. Kligman, known for his work on topical retinoids, used this term to describe skincare products that provided therapeutic benefits to the skin above and beyond what would be seen with simple cosmetics.

Almost **30 years after** the term cosmeceutical was coined, this category of skincare products is **still not recognized** by the Food and Drug Administration.

Dr. Kligman defined cosmeceuticals as "a topical preparation that is sold as a cosmetic but has performance characteristics that suggest pharmaceutical action." At the time, his laboratory was conducting clinical studies confirming the anti-aging effects of tretinoin and later retinol. Cosmetic benefits such as these had never been seen with any topical preparation before, thus their discovery was groundbreaking at the time.

Studies conducted in the laboratory of John Voorhees, M.D., further delineated the cellular and molecular mechanisms whereby topical forms of vitamin A could improve aging skin. Their work demonstrated that retinoids improved skin's appearance by regulating transcription factors responsible for maintaining collagen homeostasis. This extensive body of knowledge about how topical forms of vitamin A rejuvenated skin put these products into a category of their own.

The discovery of alpha hydroxy acids for exfoliation and skin rejuvenation by Eugene Van Scott, M.D., and Ruey Yu, Ph.D., added another highly effective group of cosmetic products to the cosmeceutical category. Several years later, Sheldon Pinnell, M.D., developed and evaluated various forms of topical vitamin C and showed these products could be used for photoprotection as well as skin rejuvenation.

Thus, the use of the term cosmeceutical made perfect sense, as it was descriptive of this new breed of cosmetic products that had benefits beyond simple cosmetic effects but were not exactly pharmaceuticals.

Cosmeceuticals everywhere

Today the word cosmeceutical is a household term. It is found in Webster's dictionary and is used widely by consumers who seek products deemed as such for their therapeutic value. The term cosmeceutical is steeped in the medical literature and is the subject of scientific publications, lectures and textbooks. Some of our more entrepreneurial colleagues have even marketed entire skincare lines that boast the term cosmeceutical.

In view of its widespread use, it is interesting that almost 30 years after the term was coined, this category of skincare products is still not recognized by the Food and Drug Administration. This is because the Federal Food, Drug and Cosmetic Act (FD&C Act) differentiates cosmetics from drugs based on their intended use and ability to affect structure and function. Cosmetics are products applied to the skin that are intended to beautify, promote attractiveness and alter appearance. Drugs are intended to mitigate, treat or prevent disease by affecting structure and function.

These definitions are important because of the vast difference in the way cosmetics and drugs are regulated. While cosmeceuticals have consistently been shown to be safe over years of marketing, clearly these modern-day products have characteristics of both cosmetics and drugs in terms of their effects on skin. There is concern that the use of the term cosmeceutical is deceiving to consumers who think these products are held to the same standards as drugs and are regulated by the FDA as such.

This is a valid concern in that we know that while many cosmeceuticals are fully tested there are unfortunately just as many that are not. One solution might be for the Federal Food, Drug and Cosmetic Act to be updated and include a new category of products that is somewhere in between a drug and a cosmetic. The term "active cosmetics" could be used to describe these products implying that they are still cosmetics but that they have beneficial active ingredients.

Once established it would be prudent to develop criteria for testing active cosmetics so that dermatologists and consumers would be assured that the products they are recommending and buying are effective, and that the marketing claims being made are substantiated. DT

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INTRODUCING

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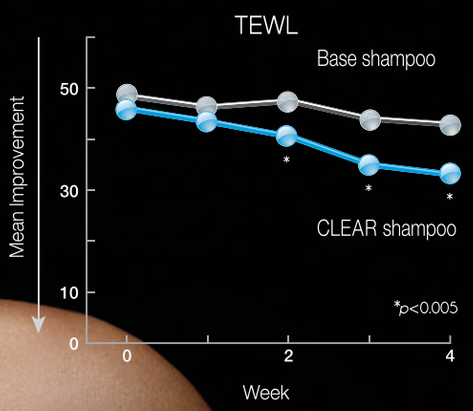

Randomized, double-blind, half-head study (N=146). CLEAR was proven significantly superior at weeks 2-4.

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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.

Lasting marks

My patient had a complication. Does that mean I was negligent?

Dr. Laser has been doing laser procedures for more than a decade. He has a great reputation and thousands of happy patients. Two years ago he performed a laser procedure on a patient who, unfortunately, scarred afterward. The procedure was handled in the same manner as hundreds of other similar procedures performed by Dr. Laser. He also obtained a signed consent form from his patient warning her of the risk of scarring.

The **standard of care is** defined by some as whatever an expert witness says it is, and **what a jury will believe.**

The patient sued Dr. Laser, claiming he was negligent in inducing her scar. She claimed that causing a scar is not within the standard of care and demanded $1 million for this incident. Dr. Laser is mystified. Was he negligent? Did he perform within the standard of care?

Four elements of negligence

Any analysis of physician negligence must begin with a legal description of the elements of negligence. There are four required elements for a cause of action in negligence: duty, breach of duty, causation, and damages. The suing plaintiff must show the presence of all four elements to be successful in her claim.

The duty of a physician performing cutaneous laser surgery is to perform it in accordance with the standard of care. Although elements of a cause of action in negligence are derived from formal legal textbooks, the standard of care is not necessarily derived from any well-known textbook. It is also not articulated by any judge. The standard of care is defined by some as whatever an expert witness says it is, and what a jury will believe.

In a case against any dermatologist performing a laser procedure, the physician must have the knowledge and skill ordinarily possessed by a specialist in that field, and have used the care and skill ordinarily possessed by a specialist in that field in the same or similar locality under similar circumstances. A failure to fulfill such a duty may lead to loss of a lawsuit by the dermatologist.

If the jury accepts the notion that Dr. Laser mismanaged the case and that the negligence led to the patient's damage, then liability will ensue. Conversely, if the jury believes an expert who testifies for a defendant doctor, then the standard of care in that case has been met.

Meeting standard of care

In this view, the standard of care is a pragmatic concept, decided case by case, and based on the testimony of an expert physician. The dermatologist is expected to perform a laser procedure in a manner of a reasonable physician. He need not be the best in his field; he need only perform the procedure in a manner that is considered by an objective standard as reasonable.

Where there are two or more recognized methods of treating the same condition, a physician does not fall below the standard of care by using any of the acceptable methods even if one method turns out to be less effective than another method. Finally, in many jurisdictions, an unfavorable result due to an "error in judgment" by a physician is not itself a violation of the standard of care if the physician acted appropriately prior to exercising professional judgment. The same concept would apply to a complication. That a complication occurred does not *de facto* imply negligence.

Evidence of the standard of care in a specific malpractice case includes laws, regulations, and guidelines for practice — which represent a consensus among professionals on a topic involving diagnosis or treatment — and the medical literature including peer-reviewed articles and authoritative texts. In addition, an expert view is crucial. Although the standard of care may vary from state to state, it is typically defined as a national standard by the profession at large.

Most commonly for litigation purposes, expert witnesses articulate the standard of care. The basis of the expert witness and the origin of the standard of care, is grounded in the following:

1) The witness' personal practice; and/or
2) The practice of others that he has observed in his experience; and/or
3) Medical literature in recognized publications; and/or
4) Statutes and/or legislative rules; and/or
5) Courses where the subject is discussed and taught in a well-defined manner.

The standard of care is the way in which the majority of the physicians in a similar medical community would practice. It is the method by which other laser physicians deal with their daily performance of laser surgery. If the expert herself does not practice like the majority of other physicians, then the expert will have a difficult time explaining why the majority of the medical community does not practice according to her ways.

Nothing stops Dr. Laser from being sued. If he has practiced under a reasonable standard of care, however, he is not likely to lose the lawsuit. DT

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 *IMS, Sept. 2012 LOC AD DT Rev.2 01/13

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CUTANEOUS ONCOLOGY

Combined education may increase guideline compliance

Melanoma Research AUGUST 2013

TO BOOST National Comprehensive Cancer Network (NCCN) guideline compliance when surgically treating cutaneous melanoma, it is necessary to offer combined patient and physician education, as well as region-specific melanoma care, according to findings published in the August issue of *Melanoma Research*.

The NCCN has issued guidelines for managing cutaneous malignant melanoma related to resection margins (RMs) and regional staging. The study's objective was to measure adherence to the recommendations in the U.S. population.

Using The Surveillance, Epidemiology and End-Results database, researchers targeted 60,194 patients with malignant melanoma from 2004 to 2008. Factors that were projecting RM<1 cm and noncompliance with sentinel lymph node biopsy (SLNB) were noted for the study.

The study population's median age was 60 years; most patients had RM <1 cm (58 percent). Only 53 percent of qualifying patients had undergone SLNB.

Sixty-nine percent of patients with positive SLNB and 78 percent of those with palpable lymphadenopathy underwent regional nodal dissection.

Researchers noted indicators suggestive of noncompliance with SLNB guidance included age of 60 or older, T1 stage, head and primary, and RM <1 cm.

http://journals.lww.com/melanomaresearch/Abstract/2013/08000/Compliance_with_guidelines_in_the_surgical.4.aspx

Potential link between melanoma, other cancers scrutinized

Ecancermedicalscience MAY 2013

THERE MAY BE A RELATIONSHIP between malignant melanoma and nonskin cancers, according to a study published in the May issue of *Ecancermedicalscience*.

Researchers with University Magna Graecia, Catanzaro, Italy, and Clinica Dermatologica, University of Rome, Italy, sought to map the links between malignant melanoma and noncutaneous malignancies to find possible connections. Using a melanoma database, study authors collected a sample of 1,720 patients to help point out patients with malignant melanoma and noncutaneous primary cancer. Included in the study were 74 patients with malignant melanoma and noncutaneous primary cancer. This matched 4.30 percent of patients with malignant melanoma in the melanoma database.

Most typical malignancies were breast cancer (24.3 percent); lymphomas (14.8 percent), renal cell carcinoma (13.5 percent), thyroid cancer (9.4 percent), and prostatic carcinoma (8.1 percent). For lymphoma patients, the majority (72.7 percent) had a non-Hodgkin lymphoma. The study revealed a high co-occurrence of numerous malignancies in malignant melanoma patients.

Researchers noted that though the coexistence of malignant melanoma and noncutaneous primary cancer may be mere coincidence, they suggest

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

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several possible connections. One such example relates to recent studies that have shown a genetic tendency to have coexisting malignant melanoma and kidney cancer in the same patient. Also, in thyroid carcinoma, BRAF mutations have been identified. In female patients, researchers discovered a significant prevalence of multiple malignancies (60.8 percent). Investigators also noted pre-existing cancer can impact the immune system and help foster development of a secondary malignancy.

http://ecancer.org/journal/7/full/315-appearance-of-malignant-melanoma-after-a-non-cutaneous-cancer-diagnosis.php

COSMETIC DERMATOLOGY

Laser and ultrasound aid in facial rejuvenation

Aesthetic Plastic Surgery JUNE 2013

A SINGLE TREATMENT combining fractional ablative carbon dioxide (CO_2) laser and acoustic pressure ultrasound technology for transepidermal delivery of cosmeceuticals may be beneficial in treating facial rejuvenation, a study published in the July issue of *Aesthetic Plastic Surgery* suggests.

Researchers aimed to determine the efficacy and safety of a new facial rejuvenation procedure that uses a fractional CO_2 laser, an ultrasound emitter, and a cosmeceutical to be applied during surgery.

For the double-blind randomized prospective study, 14 patients were recruited. For each of the patients, half of the face was treated using a fractional CO_2 laser; the other half of the face had the same laser and acoustic pressure ultrasound treatment for transepidermal application of cosmeceuticals. Authors measured effectiveness of each treatment.

Results were based off photos taken prior to treatment, as well as one, two and six months following. Researchers noted possible adverse events and complications.

Both treatments showed notable improvements for all factors assessed ($P<0.001$). The combined ultrasound and cosmeceutical treatment yielded higher scores for decreased fine lines and wrinkles and for facial aging at 6 months ($P<0.01$), producing an approximately 80 percent enhancement in facial aging. No adverse events were reported.

Most patients (86 percent) reported being satisfied or very satisfied with results.

http://link.springer.com/article/10.1007/s00266-013-0183-4

Pretreatment of aging skin enhances appearance long-term

Journal der Deutschen Dermatologischen Gesellschaft JULY 2013

PROPER PRETREATMENT such as microneedling, microdermabrasion and fractional lasers help to promote combined effects and may enhance skin appearance long-term, according to a study published in the July issue of *Journal der Deutschen Dermatologischen Gesellschaft*.

Researchers in Germany reviewed data on photodynamic therapy (PDT) for skin rejuvenation to devise appropriate techniques for treatment. Prior to treating, investigators conducted dermatologic exams to rule out potential tumors. Authors advised noting the extent of sun damage via an evaluation scale prior to starting any PDT.

When treating the face, microneedling may be advised to boost the effectiveness of the photosensitizer. Immediately after treatment and on the first day of treatment, cooling with physiologic saline compresses, thermal water or thermal water gel, cold cream and/or cool pads is recommended as after-care. In the days after, products for wound and scar care may be used.

Compared with the face and neck, on the neck and décolleté fewer sebaceous glands and other skin appendages are found. Select possible pretreatments carefully, as re-epithelization is poor and requires more time. The use of fractional ablative laser systems or microneedling is helpful, while chemical peeling as pre-treatment is possible.

Related to frequency of PDT treatments, researchers noted there are no limitations. Often, up to three treatments in three- to six-month intervals are conducted until positive outcomes are realized.

For aesthetic indications, a four-week interval between sessions is advised, or longer when other combinations of pretreatments are used.

http://onlinelibrary.wiley.com/doi/10.1111/ddg.12119/abstract

CLINICAL DERMATOLOGY

Derm surgeons handle most skin repairs in Medicare patients

Journal of the American Academy of Dermatology MAY 2013

DERMATOLOGIC SURGEONS conduct the greatest numbers of skin repairs among the Medicare population, according to findings reported in the May issue of the *Journal of the American Academy of Dermatology*.

Researchers with Mountain West Dermatology, Grand Junction, Colo., reviewed the percentage of skin reconstruction claims submitted to Medicare via dermatologists as compared to other specialists. Using the Medicare Physician Supplier Procedure Master File and focusing on years 2004 to 2009, investigators assessed the amount of layered closures, grafts and flaps performed according to specialty.

Among Medicare recipients in 2009, dermatologic surgeons' claims comprised 55.5 percent of local tissue rearrangements, 57.5 percent of full-thickness skin grafts, 60.8 percent of intermediate closures, and 75.1 percent of complex repairs.

Aside from simple repairs, split-thickness skin grafts and interpolation flaps, dermatologic surgeons charged for most of the skin reconstructions documented. With regard to reconstructions of aesthetically significant areas of the head and neck — such as ears, eyes, nose, and lips — dermatologic surgery claims were responsible for more of these compared with other fields, such as plastic surgery.

http://www.jaad.org/article/S0190-9622(13)00092-3/abstract

Zinc oxide textiles improve atopic dermatitis symptoms

Clinical, Cosmetic and Investigational Dermatology MAY 2013

ZINC OXIDE TEXTILES offer reasonable biocompatibility and are accepted well by atopic dermatitis (AD) patients, according to a study published in the May issue of *Clinical, Cosmetic and Investigational Dermatology.*

Researchers with University Medical Center Jena, Jena, Germany, examined how zinc oxide-functionalized textile fibers influence oxidative stress in AD *in vitro* and *in vivo*. The antibacterial effect and biocompatibility of the zinc textile also was assessed in vitro.

Findings showed a swift enhancement of AD severity, pruritus, and sleeping ability for Patients with AD who wore the zinc oxide textiles for three consecutive nights demonstrated rapid improvement in AD severity, pruritus and subjective sleep quality. Study authors suggested this may be related to the high antioxidative capacity of the zinc oxide textile and its potentially strong antibacterial activity.

http://www.dovepress.com/skin-protective-effects-of-a-zinc-oxide-functionalized-textile-and-its-peer-reviewed-article-CCID

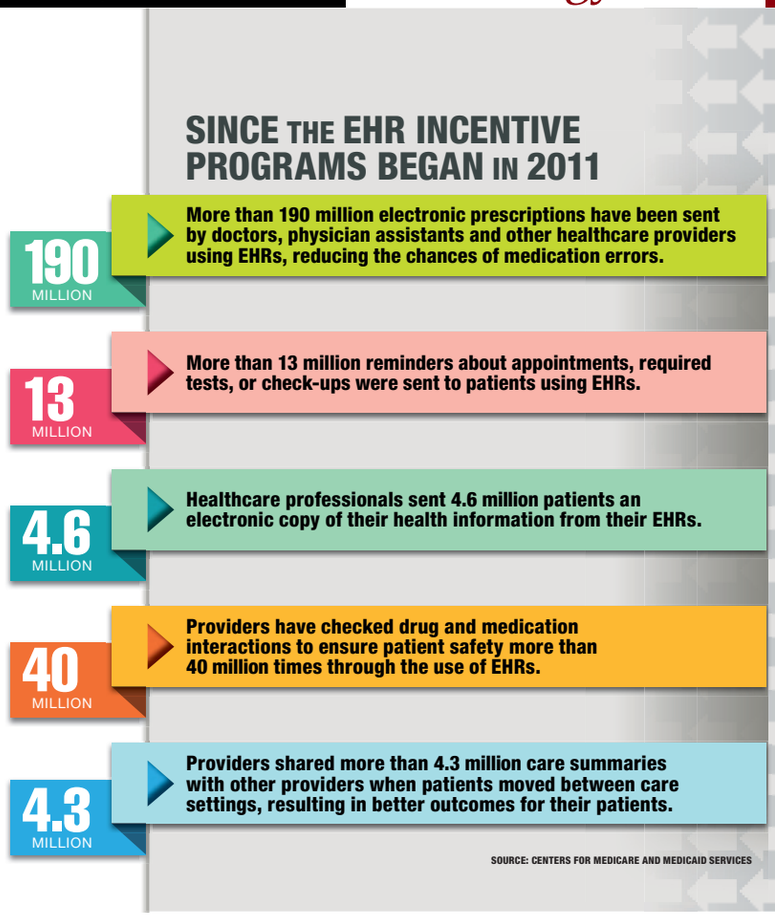
EHRs benefit patients and doctors, CMS says

Baltimore — The adoption of electronic health records (EHRs) by physicians and hospitals is not only benefiting the patient, but the healthcare provider, too, according to new data from the Centers for Medicare and Medicaid Services (CMS).

About 80 percent of eligible hospitals and more than 50 percent of eligible professionals who use EHRs have received incentive payments from Medicare or Medicaid, CMS reported recently in a news release. The payments are made possible through Medicare and Medicaid EHR incentive programs.

By using EHRs, patients have more access to their health records and the records can be easily and securely shared between healthcare providers.

"More patients than ever before are seeing the benefits of their providers using electronic health records to help better coordinate and manage their care," Farzad Mostashari, M.D., national coordinator for health information technology, said in the release. "These data show that health care professionals are not only adopting electronic health records rapidly, they're also using them to improve care." DT



RESEARCH NEWS

More skin cancer tumors may mean better survival

International report — Patients with skin cancer have better odds of survival if they have more than one primary tumor, according to results of a recent study.

Researchers examined 2,372 patients with single primary melanomas and 1,206 patients with multiple primary melanomas. They were enrolled in the Genes, Environment and Melanoma study from registries in Australia, Canada, Italy and the United States, according to the study.

Investigators analyzed DNA and tissue samples from patients to establish the number of tumors and mutations each patient had, the thickness of the tumors, how actively tumors were growing and whether tumor surface had broken. Participants also answered questionnaires about family history, personal history and lifestyle.

If tumors created an ulcer in the dermis, researchers found, surviving from melanoma was less likely. Tumor thickness was the most significant factor in survival, as patients with tumors that were 4 mm or more into the dermis were 7.7 times more likely to die than those patients with tumors less than 1 mm into the dermis.

Patients with multiple primary tumors whose tumors went 4 mm or deeper into the dermis were nearly three times as likely to die than patients with tumors at only 1 mm, according to a news release. Patients with a single primary tumor that was 4 mm or deeper were 13.6 times more likely to die than patients with a tumor of only 1 mm.

"It seems that those people with multiple melanoma have some sort of native immune factor that's helping them," Marianne Berwick, Ph.D., co-author and professor of epidemiology at University of New Mexico Cancer Center, said in a statement. "It's keeping the melanoma in check."

The research team is planning additional studies to find immune biomarkers and examine how sun exposure impacts skin cancer survival, as well as study tumors in greater detail.

The findings were published online June 19 in *JAMA Dermatology*. DT

Scientists ID cause of rare skin condition

London — Scientists have identified mutations in the AQP5 gene, which encodes a water channel protein known as aquaporin 5, as the underlying cause of diffuse non-epidermolytic palmoplantar keratoderma (NEPPK).

The discovery offers further insight into how the skin barrier functions and may help direct future investigations into other conditions, say the researchers from Queen Mary, University of London.

The research team analyzed DNA from a population of British and Swedish families in which the skin condition is much more prevalent. Among the general population, it is estimated that one in 40,000 may carry the genetic mutation, but in northern Sweden the rate is up to one in 200, according to a news release.

"The AQP5 gene mutation appears to result in a protein that has a wider channel than usual, forming a bigger pore in the cell membrane allowing more water to permeate it," says study co-author Diana Blaydon, M.D., Blizard Institute at Barts and the London School of Medicine and Dentistry, Queen Mary.

The researchers noted that all individuals who inherit an AQP5 mutation will develop NEPPK; however further research is required to understand how. DT

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STRAINING FOR SUCCESS

A breakdown of 'good' versus 'bad' bacteria in acne

By John Jesitus
Senior Staff Correspondent

Miami Beach, Fla. — Even though bacteria such as *Propionibacterium acnes* share the same genus and species, an expert says, recent research suggests that different *P. acnes* strains may behave differently, which could have profound implications for acne treatment.

Previously, Whitney P. Bowe, M.D., says, "Most researchers felt comfortable classifying bacteria based on their genus and species. However, a new study adds yet another level of detail to the probiotic story." Dr. Bowe is a dermatologist based in New York City and Westchester, N.Y. She is clinical assistant professor of dermatology, State University of New York Downstate Medical Center.

Dr. Bowe

The study, conducted at the University of California, Los Angeles, spotlights the importance of identifying the particular strain of bacteria, not just the genus and species, she says. To characterize the population structure and diversity of *P. acnes* at the strain level, investigators compared samples from the nasal pilosebaceous units of 49 patients with acne and 52 healthy controls.

"By sequencing 66 previously unreported *P. acnes* strains and comparing 71 *P. acnes* genomes," the authors wrote, "we identified potential genetic determinants of various *P. acnes* strains in association with acne or health (Fitz-Gibbon S, Tomida S, Chiu BH, et al. *J Invest Dermatol*. 2013 Jan 21. [Epub ahead of print])."

QUICK READ

The importance of bacterial strains in acne is growing, as is the evidence behind oral probiotics for this condition.

Considering bacteria strains

In short, certain strains were strongly associated with the presence of acne, while other strains dominated in patients without acne. This suggests that, along with the quantity of bacteria present, dermatologists might have to consider the particular strains of *P. acnes* with which the patient is colonized, Dr. Bowe says. Based on this study, she adds, "One particular strain of *P. acnes* might actually protect the host from developing acne."

Going forward, "We need additional research to identify which strains and species are most beneficial not only for acne, but also for other chronic diseases such as rosacea and atopic dermatitis."

Dermatologists must explore the best mode of delivery for these strains, she says. Options include topical application (creams, lotions, cleansers), and oral supplementation (capsules, lozenges, and probiotic-containing foods, such as yogurt).

In the latter area, a Korean study has demonstrated that patients with acne who drank fermented milk fortified with lactoferrin daily for 12 weeks experienced significant improvement in lesion counts and clinical acne grades, as well as reductions in sebum levels, versus those who drank fermented

STRAINING FOR SUCCESS see page 16

Quotable

"Chronic immunosuppressive therapy is clearly becoming the standard of care in psoriasis."

Craig Leonardi, M.D.
St. Louis

On advancement in therapies for psoriasis

See story, page 18

FDA OKs application for new rosacea treatment

DT Extra Signum Dermatologix, a private biopharmaceutical company, recently received clearance from the Food and Drug Administration for its Investigational New Drug application for SIG990, a topical treatment aimed at treating rosacea, according to a news release. SIG990 targets erythema and inflammatory lesions. The drug is an isoprenylcysteine analog that modulates toll-like receptor and G-protein signaling. It has been tested in *in vitro* cell-based assays and *in vivo* topical inflammatory animal models.

Source: PR Newswire

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voice of the dermatologist

"In my opinion, **the TNF antagonists remain the drugs of first choice** and they do so because they treat the range of comorbidities associated with psoriasis such as psoriatic arthritis, and they are generally accepted to be cardioprotective."

Craig Leonardi, M.D., Saint Louis
page 18

STRAINING FOR SUCCESS:

Identifying beneficial strains of bacteria when treating acne from page 14

milk without the added lactoferrin (Kim J, Ko Y, Park YK, et al. *Nutrition*. 2010;26:902-909). Although the lactoferrin-enriched product achieved better results, Dr. Bowe says, "The benefits observed in patients who drank the unaccompanied probiotic drink suggest that probiotics might play an adjuvant role in acne therapy."

"One particular strain of *P. acnes* might actually protect the host from developing acne."

Whitney P. Bowe, M.D.
New York

Oral probiotics impact the gut-brain-skin axis (Bowe WP, Logan AC. *Gut Pathog*. 2011;3(1):1). More specifically, Dr. Bowe says, probiotics and their metabolites interact with gut associated lymphoid tissue (GALT), which makes up nearly 70 percent of the immune system. "Through this interaction, the immune system learns to make good decisions about how it will respond to pathogens, allergens, or commensal bacteria in the future."

Inflammation impact

On a broader level, she says, psychological stress such as anxiety or depression — alone or combined with the consumption of processed comfort foods lacking in fiber — slows gut motility and changes the gastrointestinal flora by increasing the ratio of "unhealthy" organisms to healthy ones.

"In turn, this leads to increased intestinal permeability." In this regard, Dr. Bowe says, receptors on human intestinal cells recognize bacteria and bacterial cell wall components. When these receptors encounter healthy bacteria, "The gut barrier remains intact. But when these receptors encounter unhealthy bacteria, it impacts the junctions between intestinal cells, causing a 'leaky' gut."

When this happens, systemic inflammation, and markers thereof, increase, Dr. Bowe says. Other consequences include elevation of substance P, and a decrease in insulin sensitivity. In people already genetically predisposed to acne or rosacea, "This cascade is believed to influence the skin and potentially exacerbate these conditions," she says.

Additionally, studies have shown that oral probiotics regulate the release of inflammatory cytokines within the skin (Hacini-Rachinel F, Gheit H, Le Luduec JB, et al. *PLoS One*. 2009;4(3):e4903) and improve insulin sensitivity in animal models (Hsieh FC, Lee CL, Chai CY, et al. *Nutr Metab (Lond)*. 2013;10(1):35). "These findings are relevant in light of recent studies linking high glycemic-index diets with acne," Dr. Bowe says. DT

Disclosures: Dr. Bowe is a co-inventor of patent USPN 8,415,289 Bacterial-Derived BLIS for treatment of acne. She recently filed a Return to Inventor Application (UPENN Docket No. S4013, supported by the University of Pennsylvania).

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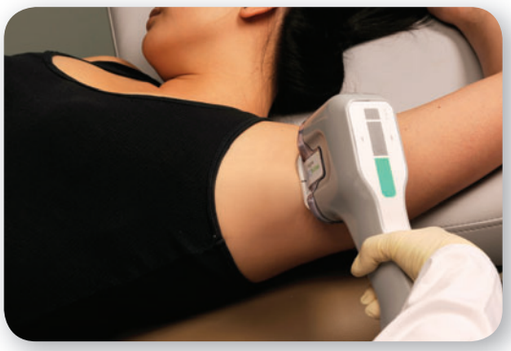

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SYSTEMIC EVOLUTION

More research into psoriasis therapies results in improved safety, efficacy

By Ilya Petrou, M.D.
Senior Staff Correspondent

Wailea, Hawaii — Systemic treatments of psoriasis are rapidly evolving as pharmaceutical companies continue their research to discover safer, more tolerable systemic medications for patients.

Though some of the once hopeful drugs have come and gone, one expert says that the future is promising as emerging drugs raise the bar in terms of better efficacy and safety profile.

"Chronic immunosuppressive therapy is clearly becoming the standard of care in psoriasis, and the more drug development that occurs, the better it is for our patients and also our specialty. It's all right that we have lost a few drugs over the years because this is a process of natural selection. The drugs that have remained however are looking very good," says Craig Leonardi, M.D., clinical professor of dermatology, at Saint Louis University School of Medicine, St. Louis.

Alefacept, (Amevive, Astellas Pharma) efalizumab (Raptiva, Genentech) and briakinumab (Abbott) are three drugs that did not stand the test of time due to efficacy and/or safety issues, Dr. Leonardi, who spoke at MauiDerm, says.

However, the majority of new drugs coming out are better and continue to improve. They include etanercept (Enbrel, Amgen/Pfizer), infliximab (Remicade, Johnson & Johnson), adalimumab (Humira, Abbott), and ustekinumab (Stelara, Janssen Biotech), according to Dr. Leonardi.

> **"Chronic** immunosuppressive therapy is **clearly** becoming the **standard** of **care** in psoriasis."
>
> **Craig Leonardi, M.D.**
> St.

QUICK READ

The future for psoriasis therapy remains bright, as newer and evolving medications steadily continue to improve in terms of safety and efficacy.

First choice of treatment

The tumor necrosis factor (TNF) antagonists are the most commonly used systemic medications in patients with severe psoriasis and, according to Dr. Leonardi, this class of drug may be the safest choice of therapy currently. Moreover, most of these drugs are self-injected and easily administered, when compared to intravenously administered medications, such as infliximab.

"In my opinion, the TNF antagonists remain the drugs of first choice and they do so because they treat the range of comorbidities associated with psoriasis such as psoriatic arthritis, and they are generally accepted to be cardioprotective," he says. "In addition, there are over 2 million patients worldwide who are on these therapies right now, so there is a familiarity with the way the drugs perform as well as their established safety profiles."

Due to increased exposure to systemic immunosuppressants particularly with long-term therapy, however, psoriasis patients should be screened for infection-related issues such as hepatitis, Dr. Leonardi cautions. It is possible that current guidelines regarding clearing a patient for administration of a given systemic medication or inclusion criteria for future trials may change.

Screening for hepatitis B

Currently, various practice guidelines and recommendations for hepatitis B virus screening in patients are being considered for long-term immunosuppressive therapy. Although the Food and Drug Administration warns against all TNF-alpha inhibitor therapy in patients with hepatitis B infection, the American Academy of Dermatology only recommends hepatitis B screening in the "appropriate setting," Dr. Leonardi says. The American College of Rheumatology does not recommend a universal screening but only screening in "high-risk" patients and those patients treated with specific drugs.

Hepatitis B infection during immunosuppressive therapy could have serious outcomes, Dr. Leonardi says, adding it would be wise to practice universal hepatitis B screening prior to long-term immunosuppressive drug therapy. He notes that dermatologists should not treat hepatitis B patients with any systemic immunosuppressive drugs without having a hepatologist involved in the planning and management.

"Patients need to be treated for their hepatitis B infection before embarking on immunosuppressive therapy, and a timely prophylactic antiviral therapy could even improve outcomes," he says.

Interestingly, hepatitis C is considered to be perfectly compatible with the TNF antagonist class of drugs, Dr. Leonardi says, and while TNF blockade makes hepatitis B worse, the drug can often help improve the hepatitis C status. Though counterintuitive, he says the actual viral load in the blood decreases in those patients with hepatitis C who also take TNF antagonists, in some cases dramatically.

"There are several different TNF antagonists that are showing promise right now and there surely will be more in the pipeline. Many people get wrapped up in these immunosuppressive drugs and the companies, but the fact is, we want good and safe medications for our patients and these agents appear to be doing well and are getting better all the time," Dr. Leonardi says. DT

Disclosures: Dr. Leonardi is a consultant for Abbott, Amgen, Centocor, Pfizer and Eli Lilly. He has been an investigator for Abbott, Amgen, Genentech, Centocor, Eli Lilly, Pfizer and Novartis. He is on the speakers' bureau for Abbott and Amgen.

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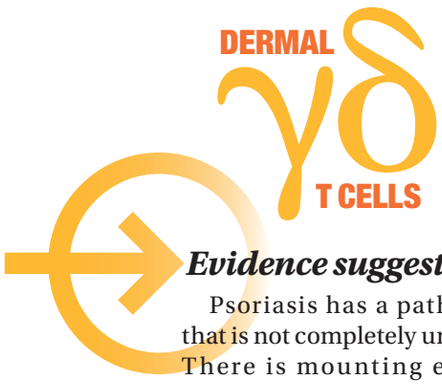

Evidence suggests psoriasis is T-cell driven from page 1

Psoriasis has a pathogenesis that is not completely understood. There is mounting evidence, however, suggesting the disease is T-cell driven, specifically T helper (Th) 1 and Th17 cells, both of which have been shown to be involved in the pathogenesis of psoriasis. The pro-inflammatory cytokines produced by these T cells including tumor necrosis factor- alpha (TNF-alpha), interleukin (IL)-17, IL-22, IL-23, IL-12 and IL-1beta have all been implicated in the pathogenesis of the disease.

> "Dermal gamma delta T cells ... **could prove to be** another viable target and a **new focus** for **future** therapies in psoriasis."
>
> **Jun Yan, M.D., Ph.D.**
> Louisville, Ky.

"New and emerging treatments for psoriasis such as novel biologic agents have been developed to selectively target specific components of the immune system, such as IL-23 and IL-17," says Jun Yan, M.D., Ph.D., professor of medicine, endowed chair in translational research, co-director, Tumor Immunobiology Program, James Graham Brown Cancer Center, University of Louisville School of Medicine, Louisville, Ky. "The dermal gamma delta T cells which are found to be intricately involved in these immune pathways could prove to be another viable target and a new focus for future therapies in psoriasis."

Dr. Yan and his colleagues recently conducted a study to identify and better understand which cells and pathways in the skin are the major contributors to the inflammation typically seen in psoriasis and psoriatic lesions. To dissect the precise cellular source of IL-23 and the transcripts of which are increased in human psoriasis, Dr. Yan analyzed skin tissues of healthy individuals and patients with psoriasis, as well as murine psoriasis skin samples using immunofluorescent staining.

According to Dr. Yan, IL-23-induced skin inflammation has been primarily linked to the function of Th17 cells and related cytokines. The results of the study not only showed that IL-23 is mainly produced by dermal dendritic cells and macrophages, which is critical for IL-17 production in the skin, but also that the dermal gamma delta T cells are the major source of IL-17 upon IL-23 stimulation in the skin. In addition, Dr. Yan found that the IL-17-producing dermal gamma delta T cells are phenotypically unique.

"From the mouse model point of view, gamma delta T cells are definitely more important than Th1 and Th17 cells, and appear to be essential in the production of IL-17 and pathogenic cells in the skin following IL-23 stimulation," Dr. Yan says. "More importantly, these cells have also shown to be very much involved in the development of psoriasis. Therefore, a therapy that could specifically target and regulate dermal gamma delta T cells could be beneficial."

IL-23-induced changes in murine skin share many characteristics with human skin Dr. Yan says, including erythema, acanthosis, parakeratosis, and leukocyte infiltration. According to Dr. Yan, murine skin samples deficient of gamma delta T cells or IL-17 receptor significantly decreased IL-23-induced epidermal thickness and neutrophil infiltration, and subsequently showed decreased skin inflammation, psoriasis lesions, or psoriasis-related inflammation, suggesting again that the gamma delta T cells are key in the development of psoriasis.

Similarly in human psoriasis skin samples, the study found that gamma delta T cells are the critical cells to produce IL-17, which were massively infiltrated in psoriatic skin, accounting for approximately 30-40 percent among the whole of the CD3+ cells. However, in humans, Dr. Yan said that it is very difficult to dissect what the contribution is of Th17 cells, Th1 cells or gamma delta T cells into the disease, and that correlation studies can only be performed here.

"There is ongoing research looking at gamma delta T cells and what kind of factors could regulate those dermal gamma delta T cells in humans. It appears that this cell population would be a novel drug target for psoriasis therapy, however it is hard to say when such a drug could become available. Nevertheless, we now have a new focus for therapy in our sites, which eventually could translate into more effective treatments for psoriasis by reducing the inflammation typically seen in psoriasis and psoriatic skin," Dr. Yan says. DT

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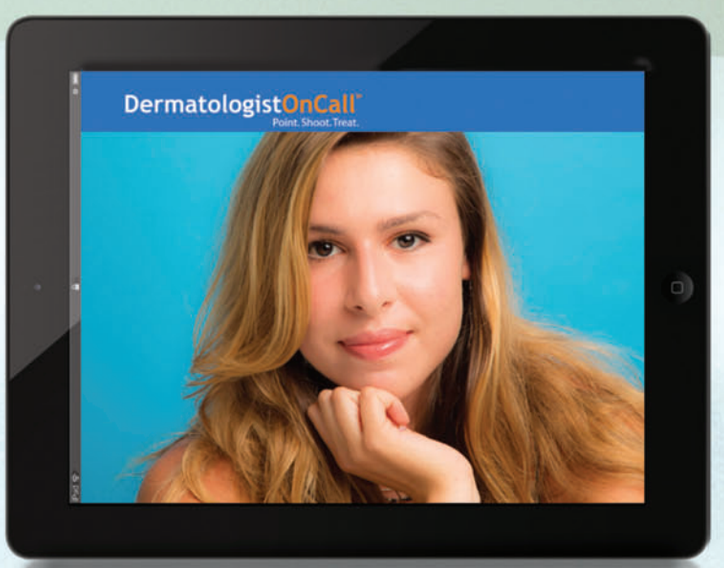

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Dermatology Times

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Advancing the art, business of aesthetics

PHYSICIANS, SURGEONS SHARE COSMETIC PEARLS, BEST BUSINESS PRACTICES

A trend in aesthetic medicine that many physicians and industry professionals are noting is the move from one-off treatments to ongoing prevention and global treatment, according to speakers at the 9th annual Vegas Cosmetic Surgery and Aesthetic Dermatology meeting.

While surgical techniques are still viable and in certain circumstances are more effective, safe and cost-effective minimally invasive approaches are gaining traction to meet the needs of consumers who are looking for a more natural look with less downtime. This appeared to be one of the themes of the conference, while another was focused on developing effective business marketing strategies targeting existing and new patients.

According to Phillipe Burnham, director of product marketing for Obagi, two groups of people will be flooding the market as the economy turns around and discretionary spending increases: One is aging baby boomers looking to improve photodamage and skin aging. Then, he says, "There's an interesting emerging group of people who are younger and are very knowledgeable about sun damage and photoaging and are looking at it as less as treatment, more as prevention."

Whether it's treatment driven or prevention and defense, the goal is a more natural global aesthetic approach, says Mikael Svensson, director of marketing, filler franchise, Merz Aesthetics.

"Patients are looking for that rejuvenation over time. The trend, more and more, is to start earlier with prevention," Mr. Svensson says. "And aesthetics is a more acceptable discussion under the umbrella of prevention."

Focus on fillers, neurotoxins

In a presentation on filler and neurotoxin treatments, Steven Dayan, M.D., F.A.C.S., a facial plastic surgeon in Chicago, says the goal of using neurotoxins and fillers isn't to remove wrinkles. It's about how to make the face more symmetric. If a person can tell a patient had work done, you fail, he says, because beauty works at a subconscious level.

He says his effort to develop a brand around this outcome is critical to fighting commoditization, which he feels is a threat to all aesthetic physicians.

"Don't charge price per unit because once you start going down that road and charging price per unit, eventually you become irrelevant," Dr. Dayan says. "(Patients will) come to you for $10 per unit but they'll go

VCS2013 see page 24

Quotable

"You can't approach men and women the same way, in terms of offering them the same range of services."

Tina Alster, M.D.
Washington

On treating men in aesthetic medicine

See story, page 40

DTExtra

Patients who undergo aesthetic treatments with soft-tissue fillers are **pleased** with the results **92 percent of the time**, according to a survey conducted by the American Academy of Dermatologic Surgery. Of the 6,300 people surveyed, **45 percent** indicated they were **"extremely satisfied"** with their soft-tissue filler procedure. There was a **10.4 percent increase** in the number of soft-tissue filler procedures performed from 2011 to 2012, from almost 831,000 to 917,000. Additionally, **53 percent** of those surveyed said they were **considering** undergoing a procedure **in the future.**

SOURCE: AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY

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VCS2013

Stay** in **tune** to **best practices** for **cosmetic treatments from page 22

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next door for $9 per unit, because you don't matter; the only thing that matters is the dollar per unit, and eventually if we all do that, we all become irrelevant."

Tracy Drumm, vice-president of aesthetic practice marketing firm IF Marketing, agreed. "Commodities compete on prices, brands compete on intangible attributes," Ms. Drumm says. She has drilled brand marketing down to three key points: experience, relationships, and outcome-based marketing.

"Don't charge price per unit because once you start going down that road ... eventually you become irrelevant."
Steven Dayan, M.D., F.A.C.S.
Chicago

Brand building

When working on building your practice's brand, you should also think about marketing campaigns and targeting specific audiences with varying media, according to Grant Stevens, M.D., F.A.C.S., owner of a plastic surgery practice in Marina Del Rey, Calif. He relayed how he uses emails, newsletters, a website, radio spots, and billboards to attract attention and build a brand around the phrase, "Freeze the Fat."

Dr. Stevens' efforts, he says, have led to a huge growth in the number of patients who come to his practice because they are interested in the CoolSculpting (Zeltiq) results from the "Freeze the Fat" campaign.

"Sixty-six percent of 'Freeze the Fat' patients were new patients," Dr. Stevens says. "Sixty-two percent of those were aesthetic neophytes and 40

percent became established patients."

Dr. Dayan says his branding strategy has also reaped him revenue rewards.

"Since we started offering subliminal differences, our revenue has gone up 113 percent. The average patient used to get around 2.1 cc of filler; now they get 3.2 cc, 59 percent of patients end up getting skincare services because the two go together. They get better outcomes because I'm giving them the result they are looking for," Dr. Dayan says.

One of the keys to implementing branding and marketing strategies is to take advantage of your existing patient base, according to Matt Steve, director of consumer marketing for Zeltiq.

> "Commodities compete on prices; **brands compete on intangible attributes.**"
>
> **Tracy Drumm**
> Chicago

Mr. Steve noted that company research has uncovered that about 40 percent of patients coming to a physician's office for CoolSculpting are new to the practice. Many may not have even had fillers or toxins, he says. In circumstances such as this, it offers physicians a chance to capture a new patient base and upsell additional products and services. Mr. Steve advised physicians to train themselves and their staff around this concept.

"If a patient calls to ask about a procedure, every single staff member has to be able to convert a patient and get them to come in for a consultation," he says.

Integrating EMRs

Sessions focused on electronic medical record (EMR) systems and adjunct software products offered ideas on how to develop more integrative practice management systems that improve patient relationships and, ultimately, practice revenues.

Successful EMR processes can integrate the pieces of a clinician's practice, from scheduling to appointment reminders, to consults, to marketing, so that all work together, according to Jerry Jacobson, CEO of PatientNow.

Also over the course of the five-day meeting, clinicians from four specialties — plastic surgery, oculoplastic surgery, dermatology and facial plastic surgery — shared research and techniques for improving the aesthetic outcomes when managing patients for blepharoplasty and rhinoplasty to the use of fillers and neuromodulators in minimizing facial aging to improving scarring resulting from procedures such as Mohs surgery.

Follow the **Dermatology Times** e-newsletters and print edition for more insight culled from this meeting. **DT**

FROM PAGE 1

Q & A RISKY Business

EXERCISE CAUTION, understand the law, and put patient safety first

By Lisette Hilton | STAFF CORRESPONDENT

IN APRIL, the Food and Drug Administration issued a warning to more than 350 medical practices that they may have purchased unapproved versions of onabotulinumtoxinA (Botox, Allergan) sent by foreign suppliers. This is the most recent alarm in a series of events dating back several years. Eight experts discussed their views on the counterfeit market at the recent Vegas Cosmetic Surgery and Aesthetic Dermatology meeting in Las Vegas. Susan Weinkle, M.D., Bradenton, Fla., who moderated the panel, summed up the group's consensus by stating, "Patient safety needs to be first and foremost. We need to use products that have been evaluated, that companies have put their research dollars behind to have data to support using them safely in our patients."

Q: *Counterfeit neuromodulators and fillers are a very important patient safety issue.* ***Have you encountered them? Have you seen your colleagues encounter them? What are your thoughts going forward dealing with this? How should the industry deal with this problem?***

Susan Weinkle, M.D.
Bradenton, Fla.

A: Amy Taub, M.D., dermatologist, Chicago: I'm in the middle of the country where people are a lot more conservative. So I wouldn't say that I've seen a lot of cases or heard about a lot in my area. The only thing that happens in my area, which I'm really shocked at, is there's a physician near me who does a lot of fillers who purchases them from a friend physician in Canada. And you know that in Canada it's quite a bit less expensive. So he's basically paying maybe $70 less per syringe for his filler than I am, and he discounts it so that he's maybe doing an injection for $400 or $450 for a cc of Restylane (hyaluronic acid, Medicis). I find that to be really unscrupulous; but it's not counterfeit — it's a different thing. I always buy direct from the vendor or their authorized dealer, and would never buy from a second party.

A: Michael Perski, M.D., plastic surgeon, Encino, Calif.: I think it's a problem, and I think that if we didn't learn anything from the Tucson, Ariz., company, Toxin Research International (TRI) that was selling animal experimental-only Botox that was used on humans by a few unscrupulous individuals — which resulted in several people being paralyzed because the number of units were probably thousands of times more than they were supposed to be — then we've learned nothing.

I think it's important, particularly in the U.S., to use U.S. products. You never know where they're coming from. I have patients who come in and say, "I have this product. Will you inject it for me? You can charge me." I advise everybody not to do that.

A: Rebecca Fitzgerald, M.D., dermatologist, Los Angeles: Anytime there's money to be made there may be someone trying to exploit that. I think we all get fliers across our fax machines for "discount" products — some with familiar names and packaging — but not sold through the regular channels. I think it's important to be aware that this is risky business and avoid it. Additionally, I practice in a big metropolitan area and on rare occasions patients have come in to the office with their own product for injection. Bad idea, as you have no idea where the product came from or what's really in the syringe. I think that you have to be very, very careful to avoid that trap.

A: Benjamin Bassichis, M.D., plastic surgeon, Dallas: We don't see a lot of that in our practice. We get the weekly fax from China, but I don't see a lot of patients with the counterfeit stuff in our practice.

A: Welf Prager, M.D., dermatologist, Hamburg, Germany: I buy products directly from the companies or from pharmacies. I do not even buy reimports that are offered through international pharmacies because there are rumors

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COUNTERFEITS:

FDA, derms combat unapproved drugs from page 1

Increasing globalization

Such efforts are necessary, she says, because the supply chain has changed.

"With globalization and many more parties involved in the manufacture and distribution of drugs, we see more opportunity for malfeasance," in forms including unapproved, counterfeit or otherwise dangerous products. Additional perils could come from adulterated drugs, stolen drugs, expired drugs and improperly stored or handled drugs.

"Counterfeiters are getting increasingly sophisticated and smart," Ms. Rothschild says. "You can't simply look at a pill or package and say, 'That's counterfeit.'" Accordingly, she offers the following suggestions for avoiding unapproved drugs and their sellers:

- "If it looks too good to be true, it probably is." Unauthorized distributors frequently send email and fax blasts touting incredible deals, she notes. If something looks questionable, Ms. Rothschild says, "Ask questions, request a pedigree from the distributor, or contact the manufacturer."
- Only purchase FDA-approved drugs. Drugs approved in other countries but not by the FDA are illegal in the United States, she says. "Even with drugs from Canada, it's difficult to know what one is getting. And anyone can put a Canadian maple leaf on their website and say 'we're Canadian.' Most of them aren't."
- Inspect and double-check. "Look at the expiration dates and lot numbers, the name of the active ingredient and routes of administration. (See: Fraudulent versions of Botox found in the United States: *http://www.fda.gov/Drugs/DrugSafety/ucm349503.htm.*) And make sure the labeling is in English."
- Monitor patient feedback. "If you're getting new adverse events that a product has not previously been associated with," she says, "consider that it could be a counterfeit product."
- Know your trading partners. "All wholesale distributors in the United States must be licensed in each state to which they distribute." State websites list this information, and the FDA has provided links to these websites at: *www.fda.gov/Drugs/DrugSafety/DrugIntegrity-*

COUNTERFEITS see page 34

from a foreign supplier owned and operated by Canada Drugs, known as Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, or Clinical Care.

COUNTERFEITS:

FDA, derms combat unapproved drugs

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andSupplyChainSecurity/ucm281446.htm. Verifying licensing info doesn't guarantee that a distributor is legitimate, Ms. Rothschild says. "But it's one of the best ways we have right now to do that."

► Eliminate the middleman, where appropriate. Though Allergan has a distributor network from whom physicians can order Botox (onabotulinumtoxinA), she says, the company drop-ships the product directly to physicians. Many practitioners don't even realize there shouldn't be a middleman in this part of the transaction.

► Report suspected counterfeiters. In this regard, Ms. Rothschild says, "We would love dermatologists' help." One of the easiest ways involves sending a message to *drugsupplychainintegrity@fda.hhs.gov*. For general questions for the Office of Drug Security, Integrity and Recalls, call 301-796-3130.

An eye on prices

Dermatologist Mary P. Lupo, M.D., adds that every time she receives a fax regarding unrealistic botulinum toxin pricing, "I give that to my local sales representative." Additionally, she says, she has seen practitioners buy perhaps three vials of legitimate Botox annually, and import everything else. When people have an active account with the legitimate manufacturer, she says, there seems to be difficulty tracking how much legitimate product they're actually using. "It's very frustrating," says Dr. Lupo, who is based in and is co-director of the Cosmetic Boot Camp.

Consumers' desire for increasingly cheaper neuromodulator injections drives the counterfeiting, adds Kenneth Beer, M.D. In his market, he says, botulinum toxin prices have fallen from $12 per unit to $9.

"What happens at $5 a unit?" Dermatologists can explain to prospective patients that their costs to purchase the product remain the same, he says. Therefore, on a rational level, "People understand that it's impossible. Nevertheless, they still purchase the product from less principled practitioners — even when they rationally know that they cannot be getting the actual product that is being advertised." Dr. Beer is a co-director of the Cosmetic Boot Camp and a dermatologist in private practice in West Palm Beach, Fla.

> "If you're getting **new adverse events** that a product has not previously been associated with, consider that **it could be a counterfeit** product."
>
> **Karen Rothschild, Esq.**
> Washington

Online dangers

Vic Narurkar, M.D., says the counterfeiting problem is not limited to FDA-regulated drugs. Regarding skincare products, he says, "There's a massive array of online distribution," some of which comes from "diverters" who buy legitimately from manufacturers, then resell products to unauthorized distributors. Dr. Narurkar is a co-director of the Cosmetic Boot Camp and associate clinical professor of dermatology, University of California, Davis.

To address these problems, manufacturers are beefing up their tracking capabilities. For example, Dr. Beer says, one vendor implemented a tracking system that in 2012 allowed the company to identify and cut off five suspicious purchasers representing millions of dollars in business. Aesthetic-sector vendors also are considering adding increasingly sophisticated tracking tools such as radiofrequency identification (RFID) chips to their products, he says.

To combat unscrupulous deep discounters, Ms. Rothschild says, "Present yourselves as responsible players — not only that you're properly trained and qualified, but also that you are getting FDA-approved products from the legitimate U.S. supply chain, which is among the safest in the world."

Along with regulating and approving drugs and medical devices, she explains, the FDA also approves the packaging, labeling and manufacturing processes used to make drugs it approves. Conversely, "If people are getting foreign drugs or even foreign versions of U.S. drugs, we do not inspect those manufacturing sites. We do not know if they are manufactured according to our quality standards," she says. **DT**

Disclosures: Dr. Lupo is a trainer and clinical investigator for Allergan, and a trainer for Medicis/Valeant, but has no ownership interests in these companies. Dr. Narurkar is a clinical investigator for Allergan, Solta and Zeltiq. Dr. Beer is an investigator and consultant for Allergan, Medicis/Valeant and Merz.

www.cosmeticbootcamp.com

For more information http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/

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voice of the dermatologist

"I think that **as we go about promoting our practices that we're aware of what the law says**, particularly the 1997 FDA Modernization Act."

Derek Jones, M.D., Los Angeles page 38

RISKY BUSINESS:

Exercise caution, understand the law, and put patient safety first from page 26

that they might be fake products. I've never had problems sticking to this rule.

A. Derek Jones, M.D., dermatologist, Los Angeles: I think that all of us probably receive emails advertising non-FDA approved counterfeit fillers or toxins. When I see those emails I now delete them. If you like the look of (Bernie) Madoff in handcuffs sitting in a jail, then buy those fillers or toxins, because that's what may happen to you. It is simply illegal.

There is no defense whatsoever. In the U.S., we should only be using FDA-approved products, preferably FDA product that is specifically approved for a cosmetic indication. There's been a bit of controversy surrounding a hyaluronic acid (HA) newcomer called Expression. It's been approved by the FDA as a surgical intranasal splint. However, it's being indirectly marketed off-label as an injectable HA for facial wrinkles and folds, although safety and efficacy have not been formally studied for this purpose. The company is advertising through histologic comparisons to Restylane and Juvéderm (Allergan), leading the M.D. to believe the indications are the same. My colleagues have seen significant adverse events with it when used as an injectable filler for wrinkles and folds. So it is possible for us to be misled regarding the safety of a product. It is critically important to understand the data and the FDA approval process, a product's specific FDA-approved indications and associated safety and efficacy data, and to critically analyze product claims.

A. Michael Kane, M.D., plastic surgeon, New York: I have patients that come into New York that want me to inject some other product that they bring in. I'm not a technician so I just don't do that. I get the fax blasts like everyone else from China and Canada for the really cheap stuff and I don't do that either. It's amazing the kind of advertisements and brochures that come across your desk.

I used to forward some of this on and I used to save some of these brochures. In fact, I was involved in the FDA's prosecution of the person behind the TRI-tox scandal because I had certain brochures that I'd kept for years. And I knew exactly what was going on there. The other thing that would amaze you if you saw the list of names of doctors who were buying TRI-tox; there are names on that list that all of us would know. I just don't get it

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Dermatology Times **presents a panel discussion (right) at the annual Vegas Cosmetic Surgery and Aesthetic Dermatology annual meeting, focusing on the growing counterfeit market, lessons learned and ethical practice pearls.**

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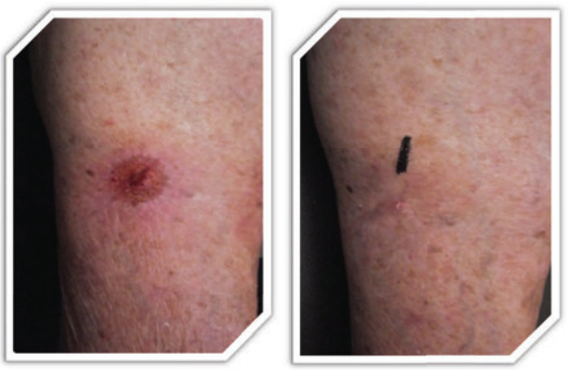

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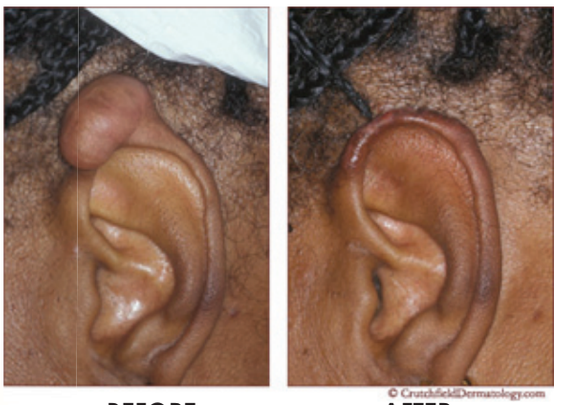

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RISKY BUSINESS:

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for a few dollars here and there.

A: Dr. Weinkle: You're right, colleagues that we recognize and know nationally. That is absolutely unscrupulous. We need to stress over and over that we've worked too long and hard to get to where we are. Patient safety needs to be first and foremost.

It's one thing as a physician to take a product that is approved for an aesthetic indication and use it off-label. We all know that when we use a neurotoxin (a neuromodulator) anywhere other than the glabella — if we use it in crow's feet, if we use it in the platysmal band, the DAO (depressor anguli oris), all the places that we choose to use it for aesthetic purposes — we're using that product off-label. But it is approved for an aesthetic indication.

Now when someone brings a hyaluronic acid into your office that has no aesthetic indication and you choose to use it off-label, you're on shaky ground. You don't have a lot of data to back you up on its safety in the dermis, the deeper planes, the face — or for aesthetic purposes. Those companies are putting the onus on us as physicians and putting our patients' safety at risk, which is really not appropriate in this day and age.

We had the wild, wild west when we started 10 years ago. Now we've learned a lot and there are rules that we need to play by.

Promoting products off-label is against the law in the United States. And we as physicians need to help back that up. It's absolutely inappropriate for companies to come to us and try to encourage us to use a product off-label for an aesthetic purpose when it's not approved for that. So I really feel in the view of patient safety, as leaders in our communities for these types of procedures, we have to stand our ground on that.

A: Dr. Jones: Susan says something very important that comes out of the 1997 FDA Modernization Act — that promoting anything we do off-label is against the law. That's true. The act states that FDA-approved devices and drugs may only be used off-label for indications that are unique to a given patient, within the context of an established physician-patient relationship. Therefore, its against the law to advertise on your website or other media for off-label purposes. So if you take it one step further, formerly is it against the law to promote botulinum toxin for aesthetic indications other than the glabellar fold? Or promoting on your website a specific type of lip filler that doesn't have FDA approval for the lips? I think the answer is yes, and a lot of M.D.s and advertising professionals don't realize this. Now, of course, digital media is just way too large for the FDA to run out and be monitoring what everyone does. But I think that as we go about promoting our practices that we're aware of what the law says, particularly the 1997 FDA Modernization Act. **DT**

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Q & A

Tailored APPROACH

AESTHETIC CARE FOR MALE PATIENTS REQUIRES DIFFERENT TACTICS BY DERMATOLOGISTS

Two experts weigh in on the nuances dermatologists should consider when addressing treatment plans with male patients.

By Lisette Hilton | STAFF CORRESPONDENT

MANY OF the differences between men and women come into play, especially regarding men's behavior and their treatment in dermatologists' offices.

Two experts have weighed in on the nuances dermatologists must consider when caring for male patients. Tina S. Alster, M.D., is director of the Washington Institute of Dermatologic Laser Surgery and clinical professor of dermatology, Georgetown University Medical Center, Washington. She will direct a focus session called "Menaissance" on male aesthetic issues at the American Society of Dermatologic Surgery annual meeting in October 2014. Her partner in practice, Terrence Keaney, M.D., also a dermatologist, directs the practice's men's center and will be on the "Menaissance" panel.

Q. ***What are key gender-related differences between male and female dermatology patients?***

A. Dr. Alster: There is a relative lack of male-specific studies in aesthetics. What we find, however, is that you can't approach men and women in the same

"Men, unlike women, are not as concerned about aging. … They tend to come in with a specific problem."

Tina Alster, M.D.
Washington

way, in terms of offering them the same range of services.

Men, unlike women, are not as concerned about aging. They are concerned, but not as much as they are about other things, whether it's rosacea, or body contouring or hair restoration and removal. They tend to come in with a specific problem, and, of course, aging is one of those, but it's not the driving force behind many men coming in for treatment.

A: Dr. Keaney: Men are very different, both biologically and behaviorally.

If you look at the biological differences between male and female (patients), men have thicker (more vascularized) skin.... They tend to develop hair in different areas of the body. In addition, there's more subcutaneous fat.

Behaviorally, men, as Dr. Alster touched upon, have different expectations, different goals.

In addition, men tend not to be the best patients in dermatology ... in that they tend to be more passive. They're less likely to ask questions. They're less likely to point out things that might concern them. So, in any approach with the male patient, you have to be a little more attentive, ask more questions and often explain in a little more detail (because men won't necessarily tell you if they don't understand).

Q: ***Let's focus on two areas: medical dermatology and cosmetic dermatology. Starting with medical dermatology, are there any specific concerns that are more prevalent among men and differences in treatment for these concerns?***

A: Dr. Alster: I had touched on one earlier, and that is rosacea. A lot of men might not know they have that condition, but they come in complaining of a red nose, which ends up being more prevalent with certain activities or ingestion of certain foods or alcohol.

(Laser therapy) ends up being a better type of treatment for men because they can see a good (result) after just a single treatment. Typically, you need at least a couple (treatments), but it's better and easier for them than applying topical agents or taking an oral medication.

A: Dr. Keaney: Males have higher rates of skin cancer than females — basal cell carcinoma, squamous cell carcinoma. But a big one that we should draw attention to is men have twice as high mortality rate with melanoma. Whether that's biology or behavior, we don't really know.

We do know that men present with larger, thicker melanomas. They are less likely to notice changes in their moles. So, in terms of general skin checks for the male patient, there is a lot more education and you have to be more careful because men are not necessarily going to come in complaining of a changing mole. You really have to do a good job examining them, as well as using some of the new available tools on the market. For example, here we have the MelaFind device (Mela Sciences), and we're being proactive about using that in our male patients, given the higher rates of mortality among men.

MALE AESTHETICS: see page 42

Q&A

Male aesthetic treatments require fresh approach

From page 41

"I tell them to use the topical product after they shave. I find that compliance increases dramatically."

Terrence Keaney, M.D.
Washington

Q: *What about the male patient on the cosmetic side?*

A: Dr. Alster: There are a lot of men who come in complaining either about having too much or too little hair. In addition, men have a higher incidence of folliculitis … so using lasers for hair removal can reduce the severity and duration of the folliculitis.

Another thing that they come in asking about is body contouring. Basically, shaping their torso — more than likely reducing fat around the girth.

A: Dr. Keaney: Even (with) the regular aging tools that we use, such as botulinum toxin and fillers, you approach the male patient much differently. (Males have different boney and muscular structures, as well as different aging goals.) For example, rather than augmenting the lips, which is commonly done in women, in the male face, often we'll apply filler along the jawline or above the brow. These are masculine features of the face that are often not considered (for treatment). Female and male patients should be treated very differently, to highlight the masculine and feminine features.

One of the (conditions we treat) that is a little more male-specific is sweating — particularly, underarm sweating. At our practice, we use both botulinum toxin and a newer device called miraDry (Miramar Labs). Male patients are less likely to come back frequently, and miraDry (results) in a permanent reduction in sweating, which occurs over two to three visits. Men like that kind of finality in terms of treatment.

A: Dr. Alster: (miraDry) is a microwave technology delivered in an outpatient setting. It typically takes under an hour for a treatment. One treatment has been shown to reduce sweating permanently by a good 55 percent and, after two sessions, upwards of 80 percent to 90 percent reduction. After two treatments, they are relatively dry and they don't have to keep coming in for repetitive treatments, as would be required by using either Botox (onabotulinumtoxinA, Allergan) or Dysport (abobotulinumtoxinA, Medicis) injections.

Q: *Do men comply as well as women with at-home treatment?*

A: Dr. Alster: (No.) We do spend time with men … reviewing how they take care of their skin. We try to let them know that we're not going to make them a slave to skincare, but basically set up an easy regimen, which typically involves cleansing the skin; putting on an antioxidant (for those people who are aging baby boomers); and then a sunscreen. (It's) basically doing a three-step approach every morning.

If they have more specific skin conditions, whether that's acne or dyspigmentation or blotchiness, we may tell them to use something else on their skin. But, by and large, we find that most men (are more likely to do a once-a-day approach, versus doing multiple things a few times a day).

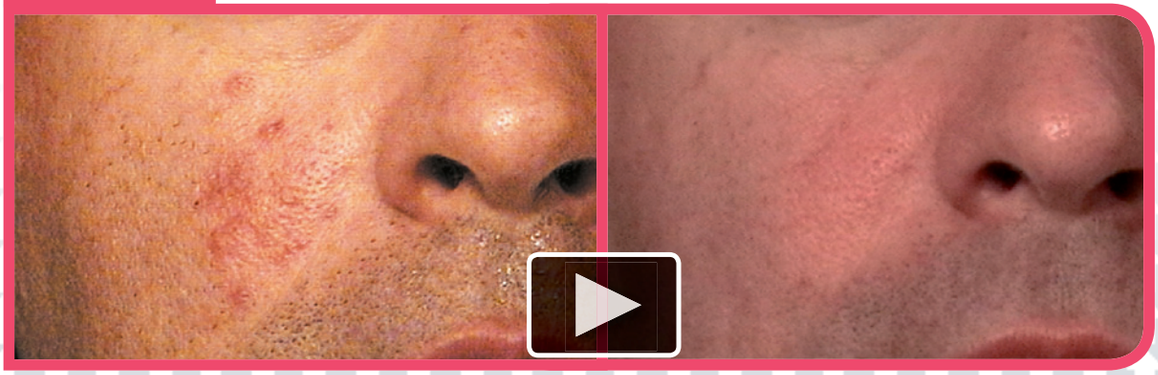
Q: *When you treat men with laser or Fraxel (Solta Medical) treatments for wrinkles or scarring, are there any nuances in your approach to men's skin?*

A: Dr. Alster: Men's skin is definitely thicker. Oftentimes, while we may use the same energy, we may apply additional passes of the Fraxel laser in particular areas, such as the cheeks or the jawline.

Q: *Is there anything else important for dermatologists to know?*

A: Dr. Keaney: Personal care product surveys show that men generally use less product on their skin than women. They're not used to putting things on their skin. When I recommend any skincare or topical prescription medication, I try to tie it to a behavior that they do every day, such as shaving. So, I say, 'Take your personal care product and put it next to your shaving cream.' Then, I tell them to use the topical product after they shave. I find that compliance increases dramatically. **DT**

VIDEO dermatologytimes.com



A male patient shown before (left) and two months after completing two vascular-specific pulsed dye laser treatments performed at six-week intervals.
(Photos: Tina Alster, M.D.)

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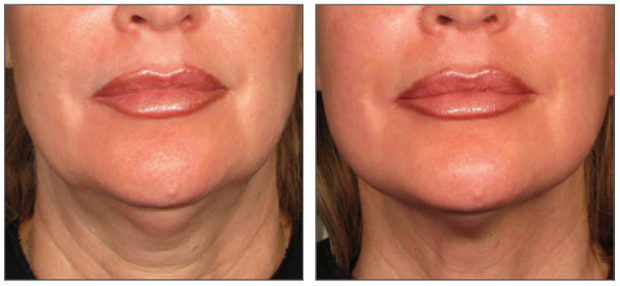

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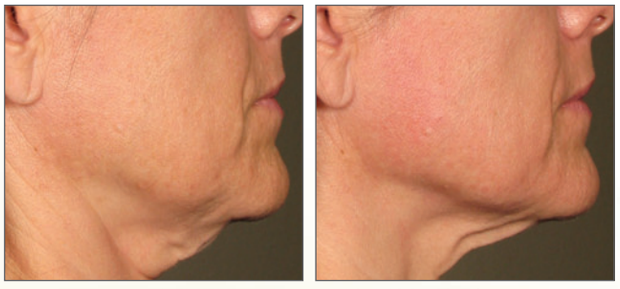

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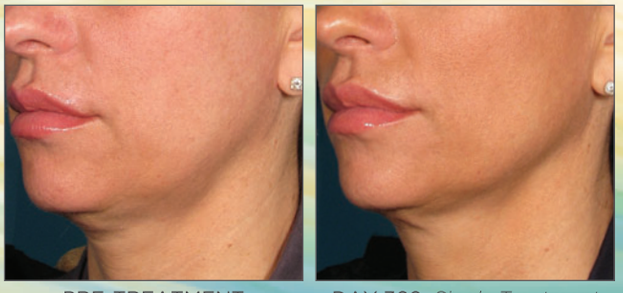

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Dermatology Times

46 PREVENTIVE MEASURES
Chemopreventive agents being explored could protect skin from developing cancer

TARGETING MUTATIONS

Treating wild-type BRAF mutated melanoma poses challenges

By Louise Gagnon
Staff Correspondent

Banff, Alberta — Various approaches are being initiated to treat wild-type, BRAF mutated melanoma, according to the director of the melanoma program and co-leader of the signal transduction program at Vanderbilt-Ingram Cancer Center in Nashville, Tenn.

Speaking here at the annual Canadian Melanoma Conference in February, medical oncologist Jeff Sosman, M.D., professor of medicine at the cancer center, discussed management approaches to melanoma where there is a BRAF, wild-type genotype. Dr. Sosman describes these forms of melanoma as heterogeneous disease.

Since the BRAF inhibitors are not effective in patients with wild-type melanoma, alternative therapeutic approaches have to be examined, Dr. Sosman says. Even when responses have been produced with the use of BRAF inhibitors, resistance typically develops within a year of treatment, underlining the need for other treatment approaches.

QUICK READ

Novel strategies are needed to treat patients with wild-type, BRAF mutated melanoma, and immunotherapy will potentially be a component of the management.

"There's no doubt that immunotherapy plays a critical role in the treatment of these patients (those with wild-type melanoma)," Dr. Sosman says. "There are many other genetic changes that make up a consistent theme about what the targeted molecules are in these patients.

"There are several populations in the BRAF wild-type. We know NRAS is a driver that causes the cancer and plays a key role. We have had difficulty getting a drug that hits the target and effectively blocks it."

Identifying common mutations

The Cancer Genome Atlas, a project funded by the National Institutes of Health that involves charting the genomic changes in various cancers — including cutaneous melanoma — has revealed that there are a number of common mutations in the BRAF, wild-type group, Dr. Sosman says.

About a third of BRAF, wild-type patients have NRAS mutations; a very small subset of patients have cKit mutant melanoma arising from mucosal, acral, and chronic, sun-damaged sites and make up another proportion of BRAF, wild-type patients. Finally, there are a number of BRAF, non-V600 mutations or BRAF fusion kinases.

"We have recently conducted whole-genome sequencing to find a BRAF mutation in exon 15 called L597R," Dr. Sosman says.

Researchers found that cells harbor BRAF mutants that are sensitive to MEK inhibitors, which serves as a basis for routine screening and a therapeutic paradigm of BRAF mutant melanoma where L597R is present (Dahlman KB, Xia J, Hutchinson K, et al. *Cancer Discovery*. 2012;2(9):791-797).

"There are a number of BRAF mutations that don't involve the V600 allele," Dr. Sosman says. "They do not inherently appear responsive to the BRAF inhibitors. Even though cKit is exceedingly rare, you should always look for it. It makes up about 15 percent of mucosal or acral melanomas, which are really rare to begin with."

TARGETING MUTATIONS see page 48

Quotable

"Though the trials with antioxidants have failed so far, we need to persevere and find a way to overcome those failures."

Sancy Leachman, M.D.
Salt Lake City

On chemopreventive agents for skin cancer

See story, page 46

ABCDEs of melanoma not applicable to all patients

DT Extra Investigators with the University of California, San Francisco, retrospectively reviewed the charts of 60 pediatric patients with melanoma and 10 with ambiguous melanocytic tumors treated as melanoma. Sixty percent of patients aged 0 to 10 years and 40 percent aged 11 to 19 years did not present with conventional ABCDE (asymmetry, border irregularity, color variegation, diameter > 6 mm and evolution). The most common symptoms were amelanosis, bleeding, "bumps," variable diameter, uniform color and *de novo* development.

Source: *Journal of the American Academy of Dermatology*

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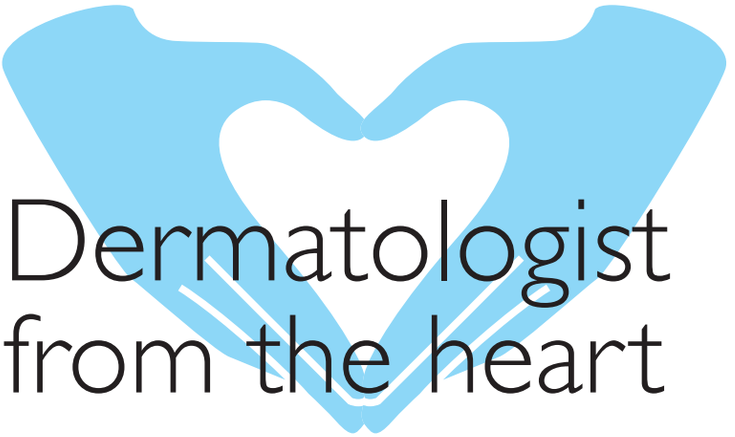

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PREVENTIVE MEASURES

Chemopreventive agents being explored could protect skin from developing cancer

By Ilya Petrou, M.D.
Senior Staff Correspondent

Miami Beach, Fla. — Efforts to prevent and chemoprevent melanoma are ongoing, and though much still needs to be done, one expert says some inroads are being made that may impact mortality, morbidity and quality of life.

"Dermatologists are in a unique position to be able to lead the field of chemoprevention because there is no other cancer that is as detectable and accessible without the use of specialized diagnostic tests as melanoma," says Sancy Leachman, M.D., director of the Melanoma and Cutaneous Oncology Program and professor of the department of dermatology, University of Utah School of Medicine, Salt lake City.

> "Agents that can increase the capacity of the cell to repair DNA are strong candidates for chemoprevention."
>
> **Sancy Leachman, M.D.**
> Salt Lake City

With the current epidemic of melanoma, the primary and secondary prevention methods in place are more important than ever to help reduce the incidence of the disease. Though still in its infancy for melanoma and skin cancer however, the concept of chemoprevention is turning heads, particularly in the dermatologic community.

QUICK READ

Researchers are homing in on developing chemoprevention agents that could help protect the skin from the development of melanoma and skin cancer.

For years, dermatologists have been practicing a form of chemoprevention, Dr. Leachman says, by treating actinic keratoses with agents such as 5-fluorouracil and imiquimod in order to prevent development of squamous cell carcinoma. According to Dr. Leachman, who spoke at the American Academy of Dermatology annual meeting, such preventive treatments could serve as a model for development of melanoma prevention agents as well.

Skin test

In terms of chemoprevention, dermatologists have an advantage in their ability to biopsy skin to determine whether a potential chemoprevention agent is having the intended effect on the target skin cell. Unfortunately, however, Dr. Leachman says the chemoprevention agents that have been explored to date have not completely gone through a rigorous scientific vetting process to show a high likelihood of succeeding while still being safe for the patient.

"The bar for treating someone preventively is much higher than for treating someone therapeutically," she says. "If you treat someone therapeutically, they have a problematic condition that warrants therapy, but in treating someone who has not yet developed the condition, the 'do no harm' philosophy is paramount."

Melanoma is one of only a few cancers with a strong environmental component, namely ultraviolet (UV) light. According to Dr. Leachman, this knowledge gives dermatologists the unique opportunity to target a UV light event (such as a beach vacation), selectively using a chemoprevention agent at the time when patients expose themselves to UV light. This is an advantage relative to chemoprevention agents that must be given on a daily basis, because it reduces the possibility of adverse side effects.

"A pulse therapy given at a set time before, during and after UV environmental exposure could be an ideal chemoprevention solution for individuals that have a predominantly indoor occupation," Dr. Leachman says. "However, for someone who is out in the sun every day, you might have to give a chemoprevention agent more often. This underscores the importance of the safety of chemoprevention agents."

There are several different classes of potential chemoprevention agents that are being studied, she says, including N-acetyl cysteine, antioxidants, aspirin, other nonsteroidal anti-inflammatory drugs (NSAIDs), and agents that enhance DNA repair, among others. The hope is that these agents can impact pathways to reduce mutations in the skin that lead to cancer.

Antioxidant analysis

Though antioxidants have been extensively studied in other cancers in the past, Dr. Leachman says that historically, antioxidants that have been used for cancer chemoprevention — such as vitamin E and selenium in prostate cancer and beta-carotene and retinoids in lung cancer — have failed.

"Though the trials with antioxidants have failed so far, we need to persevere and find a way to overcome those failures. I believe that oxidative stress is one fundamental and targetable pathway responsible for skin

PREVENTIVE MEASURES see page 48

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TARGETING MUTATIONS:

Novel strategies needed for wild-type BRAF mutated melanoma from page 44

Targeted treatments

There is no effective targeted therapy for NRAS mutant tumors or melanomas, which have unknown driver mutations, but some investigators have observed that NRAS mutation may predict benefit compared to wild-type melanomas when immunotherapy was administered.

> "Even though cKit is exceedingly rare, you should always look for it. It makes up about 15 percent of mucosal or acral melanomas."
>
> **Jeff Sosman, M.D.**
> Nashville, Tenn.

The use of MEK inhibitors alone is not sufficient to treat wild-type melanomas: One investigation in a mouse model demonstrated that MEK inhibition produced apoptosis but did not succeed in triggering cell cycle arrest. Indeed, other agents combined with MEK inhibitors will likely be a direction of treatment, Dr. Sosman says. Some data has pointed to the combination of LEE011 (CDK4 inhibitor) and MEK 162 (MEK inhibitor) to benefit patients with NRAS melanoma.

At Vanderbilt-Ingram Cancer Center, investigators are sequencing 66 genes relevant to cancer prognosis and therapy, some of which play a more relevant role for melanoma. Hundreds of exons of these genes are being targeted. The identification of mutations in melanoma to date emphasizes the role of the mitogen-activated protein kinases pathway, the pathway through which the mutations activate. **DT**

Disclosures: Dr. Sosman has served on advisory boards for GlaxoSmithKline, Bristol-Myers Squibb and Roche-Genentech. He has served as a consultant for Bristol-Myers Squibb, Roche-Genentech and Novartis.

PREVENTIVE MEASURES:

Chemopreventive agents may protect skin from cancer from page 46

cancer, particularly in melanoma," Dr. Leachman says.

For an antioxidant to be truly effective as a chemoprevention agent, she says, the agent has to be able to raise the antioxidant capacity of the cell intracellularly, where it can reduce DNA damage. Some clinicians are currently treating their patients with antioxidants such as vitamin C and E, Dr. Leachman says, but these antioxidants may not be increasing the intracellular antioxidant capacity, which is necessary to make a difference.

On the contrary, Dr. Leachman says that although these antioxidants may decrease oxidative stress extracellularly, they could have a paradoxical negative feedback effect to reduce intracellular capacity to counter oxidative stress. This could explain the previous failures of antioxidant prevention strategies.

"DNA damage plays a central role in skin cancer development, so agents that can increase the capacity of the cell to repair DNA are strong candidates for chemoprevention," Dr. Leachman says.

Testing for success

Other chemoprevention agents that could be effective are those that may be able to artificially — without the damage due to the sun — increase the tan of the skin, such as the melanocortin-1 receptor agonists. These agents can not only lead to increased pigment production and decreased damage but also increase repair.

According to Dr. Leachman, future research should systematically test each agent in a relevant animal model and demonstrate success, while at the same time, permit the design of biomarkers that can indicate whether a particular agent is having its intended effect on a pre-designated target. These biomarkers would need to be validated in a small phase 1 clinical trial, she says, to determine the potential of success of the studied agents before moving into larger chemoprevention trials, which would optimally be performed in a high-risk patient population.

"It is an exciting time on all fronts of melanoma prevention and I think we are in the position to be able to bring a truly effective and safe chemoprevention agent into existence. The hope is that these concerted efforts may ultimately culminate in helping our patients to avoid this horrible condition called melanoma," Dr. Leachman says. **DT**

Disclosures: Dr. Leachman reports no relevant financial interests.

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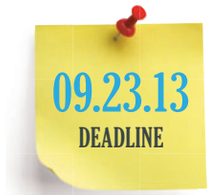

Meaningful use:

IMPORTANT DEADLINES ARE APPROACHING

By Jeffrey Bendix, Daniel R. Verdon and Rachael Zimlich
Medical Economics

Meaningful use, the government program of financial rewards and penalties for encouraging doctors to use electronic health records (EHRs), has several important deadlines approaching.

Oct. 3 is the last day doctors and other eligible professionals (EPs) can begin the attestation process to qualify for the first stage of meaningful use (MU1) in 2013 (The reporting period for MU1 attestation is 90 days).

Feb. 28, 2014, is the final deadline for reporting attestation results for 2013 and qualifying for the Medicare MU financial bonus. The final 2013 deadline for Medicaid attestation varies from state to state, so EPs need to check with their state Medicaid agency to learn their state's deadline. EPs qualifying for the first time in 2013 under the Medicare program will receive $15,000, and those qualifying under Medicaid will receive $21,250.

In addition, EPs will be able to begin attesting to the second stage of meaningful use (MU2) on **Jan. 1, 2014**. The MU2 attestation period for 2014 will be 90 days, but in 2015 and beyond will be for a full calendar year. That's because the MU certification requirements for EHR systems will change in 2014, says Robert Anthony, deputy director of the health information technology initiatives group in the Centers for Medicare and Medicaid Services(CMS). The briefer reporting period will give EPs additional time to acquire or upgrade to MU2-certified technology.

Medicaid EPs can choose any 90-day period in 2014 in which to attest, but Medicare EP attestation periods will start on **Jan. 1, April 1, July 1 or Oct. 1**.

Like MU1, qualifying for MU2 requires meeting a series of core (required) and menu (optional) objectives. A complete list of MU2 objectives is available on the CMS website at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_MeaningfulUseSpecSheet_TableContents_EPs.pdf*.

A self-directed time line showing the length of time required to demonstrate meaningful use at each stage and the maximum incentive payment for each year of participation is available at *http://go.cms.gov/14JaxOO*. DT

QUICK READ

Several important deadlines for meaningful use are fast approaching. Mark your calendars.

Quotable

"There are ways to make any goal work. The first step is to evaluate goals and see which jobs correspond."

Heidi Moawad, M.D.
Cleveland

On potential careers outside of medicine

See story, page 54

DTExtra

As the use of online networking channels increases, so do concerns about maintaining patient confidentiality. Experts suggest that **physicians bear responsibility** for online privacy breaches even if protected health information is willingly disclosed. The recommendations for maintaining an ethical online presence include: • **regularly monitor** to purge potentially harmful posts; • **post disclaimers** that discourage PHI disclosure; • offer **unbiased patient education**; • **clearly label** paid **advertisements**; •**do not require likes** for coupons; • **refrain** from **diagnosing**.

Source: *Journal of the American Academy of Dermatology*

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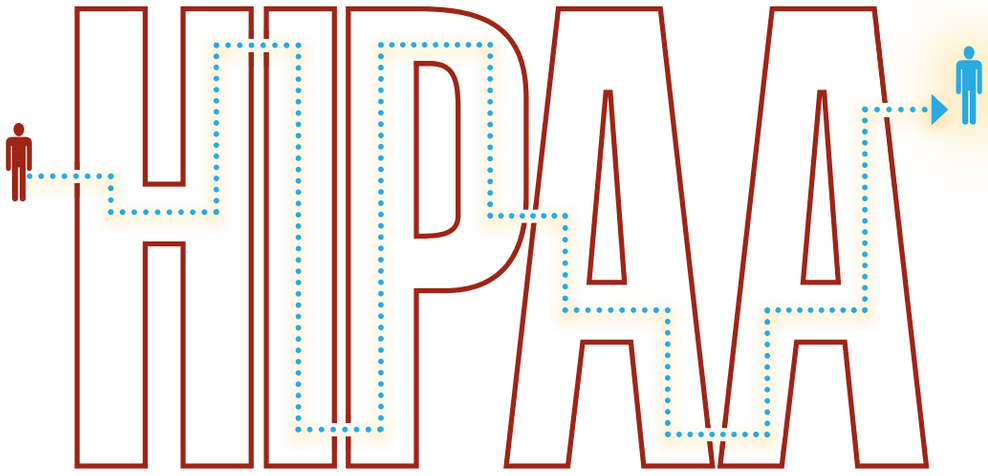
HIPAA compliance deadline looms



A QUICK GUIDE TO THE CHANGES THAT TAKE EFFECT SEPT. 23

By Jeffrey Bendix, Daniel R. Verdon and Rachael Zimlich
Medical Economics

The **penalty for unauthorized disclosure** of PHI consists of fines that range from **$100 to $50,000.**

If you haven't done so already, consider circling Sept. 23, 2013 on your calendar. That's the day that the federal government will start enforcing changes to the Health Insurance Portability and Accountability Act (HIPAA).

The changes affect everything from how you secure your patients' protected health information to the contracts you sign with vendors to what you need to tell patients about their privacy rights. Although the new regulations officially took effect in March, physicians and other entities covered by HIPAA were given six months to comply. The Department of Health and Human Services, which developed the regulations, says the updates are needed to account for the widespread use of electronic health records and other changes in health information technology that have occurred since HIPAA was enacted in 1996.

Compliance with the updated regulations require medical practices to:

- conduct a risk analysis to determine the vulnerability of electronic protected health information (PHI) to loss or theft, and document that they have done so;
- encrypt patient PHI so that it can't be used if it's lost or stolen;
- review policies and procedures for what do if PHI is lost, stolen, or inappropriately disclosed;
- review contracts with vendors and other "business associates" that have access to PHI to ensure that the vendors have proper safeguards in place to secure patient PHI.

The penalty for unauthorized disclosure of PHI consists of fines that range from $100 to $50,000, depending on the circumstances of the disclosure and the size of the practice.

The new regulations also:

- allow patients to forbid disclosure of information about a test or treatment for which the patient has paid out-of-pocket, thus requiring practices to be able to identify and separate information a patient doesn't want disclosed so that it's not accidentally sent to an insurance provider;
- permit patients to request their health information in electronic form, and require practices to comply with the request within 30 days with one 30-day extension permitted; and
- require practices to update their notice of privacy practices to include all patients' rights, and send the updated notice to all patients and posting it in the practice's office and on its website.

The regulations will be enforced by the Office of Civil Rights, part of the Department of Justice. More information about the updated HIPAA regulations is available at *www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html.*

To get ready, experts say, conduct a thorough evaluation of your practice operations to make certain you remain in compliance for data security, privacy, and reporting of breaches. **DT**

www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html.

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Q & A

BEYOND Medical Practice

AN INTERVIEW WITH AUTHOR, NEUROLOGIST HEIDI MOAWAD, M.D., ON HER BOOK 'CAREERS BEYOND CLINICAL MEDICINE'

By Brandon Glenn
Medical Economics

It's hard for physicians. Reimbursements have fallen, expenses are always rising, electronic health records often disappoint, physician burnout is up and job satisfaction is down. Heidi Moawad, M.D., a Cleveland-area neurologist and instructor at John Carroll University, gets all that. That's why she wrote *Careers Beyond Clinical Medicine*, aimed at helping physicians discover new careers that don't involve practicing medicine.

Dr. Moawad explains the first step physicians should take to explore new careers, what nonclinical occupations are typically most appealing, and what skills doctors have that make them attractive to employers.

Q: What are the most important skills that physicians gain from practicing medicine that are most easily translated to other types of work?

A: Doctors are required to master a great deal of material in medicine and patient care in order to pass medical school exams. Physicians also gain people skills and empathy through interactions with patients during times of illness and uncertainty. The hands-on work in a hospital or clinic teaches how to function well on a team. While being a doctor teaches those skills, not all doctors are the same, and every individual doctor also has an additional personal skill set, such as leadership, writing, speaking, financial insight, teaching, or innovation, that might not be directly useful or applicable in clinical medical practice. These doctor skills — knowledge, empathy and teamwork — combined with a physician's other personal skills can make a doctor a valuable asset when changing career paths.

QUICK READ

Heidi Moawad, M.D., discusses transferable medical skills, potential occupations after clinical medicine and first steps to careers outside of medicine.

Q: What are some of the most common occupations that attract physicians who stop practicing medicine?

A: Physicians, like many other professionals, often experience an evolution of professional goals and interests. There are more opportunities for lucrative nonclinical jobs than there are doctors to fill them. Some common roles for doctors include business, administration, and scientific research. But there is a long list of possibilities that are available to doctors.

Q: For physicians who are interested in exploring other careers, what's typically the first step they should take?

A: I hear from a lot of physicians who want to do something besides clinical work, but do not know where to start. I often receive emails asking me, "What jobs are available? I will do anything." While I know these doctors are trying to be flexible to avoid missing out on any opportunity, they wouldn't truly be happy with "anything."

Doctors will have greater success if they understand their options and focus on what they actually want, which is almost never truly "anything." Doctors need to begin by evaluating their personal and professional goals, which may have changed since applying to medicine school. I had one doctor tell me that he jumped straight to chapter 6 in my book to see what the salaries of nonclinical work are. It turned out that his No. 1 goal was to increase his salary and he was willing to work much more than at his clinical practice in order to achieve that goal. Other doctors want to work in global health, improving immunizations or water supply in impoverished countries, while many young mothers want to find a part-time alternative without the heavy cost of medical malpractice insurance. There are ways to make any goal work. The first step is to evaluate goals and see which jobs correspond to those goals.

Q: *Are there any types of nonclinical occupations that primary care physicians typically find most appealing?*

A: Generally, primary care physicians do well in jobs that require a big-picture outlook, such as hospital administration and public health. But I have seen many primary care physicians transition into other, more niche roles, such as grant writing and venture capital. DT

THE PQRS FORMULA

How performance ties to outcomes

By Jeffrey Bendix, Daniel R. Verdon and Rachael Zimlich
Medical Economics

Your reimbursements will be tied to outcomes in the near future. Medicare's Physician Quality Reporting System (PQRS) currently offers 0.5 percent incentive to participate this year (1 percent with Maintenance of Certification); penalties will start in 2015 as a result of the Affordable Care Act (ACA).

The overall goal of the PQRS, according to the Centers for Medicare and Medicaid Services (CMS), is to collect meaningful data that can help lead to improved patient care. The program uses a series of measures — 138 for 2013 — developed by leading physician organizations to evaluate the level of care being provided by doctors.

Measures consist of a denominator and numerator. PQRS denominators describe the eligible cases for each measure, such as the eligible patient population associated with a measure's numerator. The numerator describes the clinical action required by the measure for reporting and performance, according to CMS. To qualify, a practice simply must meet CMS' criteria for satisfactory reporting for a particular reporting period. Groups, however, must self-nominate to submit data as a group rather than individually, CMS notes.

The quality measures for 2013 PQRS address areas such as preventive care, chronic- and acute-care management, procedure-related care, and care coordination. Review the 2013 PQRS Measures List (go to *http://go.cms.gov/UmysQT*) for detailed guidance. CMS recommends considering typical clinical conditions treated, types of care provided, and quality improvement goals for 2013 when selecting measures to report. For reporting, you can choose from several options, including paper claims or registry (each with multiple reporting options), reporting through an electronic health record system, or reporting through the group practice reporting option. DT

Questions? Comments?
Give **Dermatology Times** your feedback by contacting us at **sthuerk@advanstar.com**.

Carole Foos

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Tax-saving tips

How to save up to $25K on your 2013 taxes

AS WE APPROACH the fourth quarter of the year, most of our physician clients now have a fairly good idea of what their taxable income will be for 2013. Many are wondering what they can do now to save taxes on April 15. This short article offers a few ideas that could shave tens of thousands of dollars off a 2013 income tax bill, depending on individual facts and circumstances, as well as some capital gains and planning concepts. This is especially important in 2013, as federal income and capital gains taxes are higher this year because of the fiscal cliff deal signed in January 2013, and Medicare taxes are higher because of the Affordable Care Act.

REDUCE 2013 INCOME TAXES

1. Maximize the tax benefits of your qualified retirement plan (QRP). Nearly 95 percent of physicians have some type of QRP in place. These include 401(k)s, profit-sharing plans, money purchase plans, defined benefit plans, 403(b)s, or even SEP or SIMPLE IRAs, for these purposes.

Most of these plans, however, are not maximized for deductions for the business/practice owner(s). The Pension Protection Act of 2006 improved the QRP options for practice owners. In other words, many owners may be using an "outdated" plan and forgoing further contributions and deductions permitted under the most recent rule changes. By maximizing your QRP under the new rules, you could increase your deductions significantly for 2013 and reduce your taxes on April 15, 2014.

2. Implement a fringe benefit or "hybrid" plan. Unfortunately, the vast majority of physicians begin and end their retirement planning with QRPs. Most have not analyzed, let alone implemented, any other type of benefit plan. Have you explored fringe benefit plans, non-qualified plans or "hybrid plans" in the past two years?

The unfortunate truth for many doctors is that they are unaware of plans that enjoy favorable short-term and long-term tax treatment. If you have not yet analyzed all options, we highly encourage you to do so. A number of these plans can help you reduce your taxable income in 2013 significantly… and they can be put into place in a few weeks, so it's not too late for 2013.

3. Consider a captive insurance company (CIC). CICs are used by many of the Fortune 1000 companies for a host of strategic

reasons. For a medical practice, a CIC can be equally beneficial, especially for the practice owners. Here, you actually create your own properly licensed insurance company to insure all types of risks of the practice — often those that have little coverage today. These can be economic risks (that revenues drop), business risks (that electronic records are destroyed), litigation risks (coverage for defense of harassment claims or wrongful termination), and even coverage for surgery centers and real estate.

If it is created and maintained properly, the CIC can enjoy tremendous income tax benefits that can translate into hundreds of thousands of dollars of tax savings annually.

4. Prepay 2014 expenses in 2013.

As the year winds down, we typically counsel clients to prepay for some of the following year's expenses in the present year. As long as the economic benefit from the prepayment lasts 12 months or less, this can be done. Since 2014 highest marginal tax rates will likely be the same those in 2013, this makes sense because of the benefit of the early deduction.

REDUCE TAXES ON INVESTMENTS

1. Planning for the 3.8 percent Medicare surtax.

Beginning in 2013, the tax law imposes a 3.8 percent surtax on certain passive investment income of individuals, trusts and estates. For individuals, the amount subject to the tax is the lesser of (1) net investment income (NII) or (2) the excess of a taxpayer's modified adjusted gross income (MAGI) over an applicable threshold amount.

Net investment income includes dividends, rents, interest, passive activity income, capital gains, annuities and royalties. Specifically excluded from the definition of net investment income are self-employment income, income from an active trade or business, gain on the sale of an active interest in a partnership or S corporation, IRA or qualified plan distributions and income from charitable remainder trusts. MAGI is generally the amount you report on the last line of page 1, Form 1040. The applicable threshold amounts are shown below:

- Married taxpayers filing jointly: $250,000;
- Married taxpayers filing separately: $125,000;
- All other individual taxpayers: $200,000;
- A simple example will illustrate how the tax is calculated.

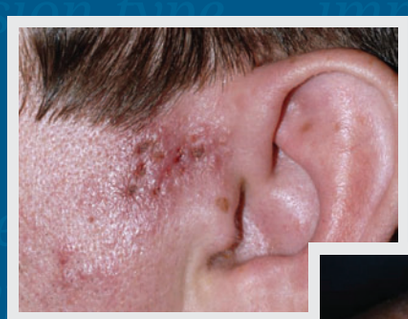
Example: Al and Barb, married taxpayers filing separately, have $300,000 of salary income and $100,000 of NII. The amount subject to the surtax is the lesser of (1) NII ($100,000) or (2) the excess of their MAGI ($400,000) over the threshold amount ($400,000 - $250,000 = $150,000). Because NII is the smaller amount, it is the base on which the tax is calculated. Thus, the amount subject to the tax is $100,000 and the surtax payable is $3,800 (0.038 x $100,000).

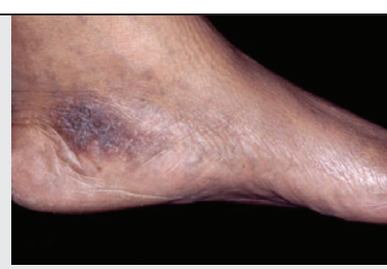
Fortunately, there are a number of effective strategies that can be used to reduce MAGI and or NII and reduce the base on which the surtax is paid. These include (1) Roth IRA conversions, (2) tax exempt bonds, (3) tax-deferred annuities, (4) life insurance, (5) oil and gas investments, (6) timing estate and trust distributions, (7) charitable remainder trusts, (8) installment sales and maximizing above-the-line deductions. We would be happy to explain how these strategies might save you large amounts of surtax.

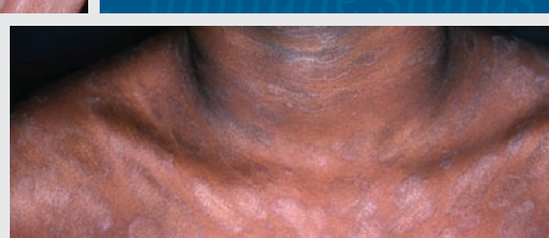
2. Use charitable giving for capital gains tax planning.

There are many ways you can make tax beneficial charitable gifts while benefiting your family as well. Charitable remainder trusts (CRTs), charitable lead trusts (CLTs), private foundations — these all can be used, within the IRS rules, to benefit charitable causes, reduce taxes and retain some benefits for families. If you have considered any of these tools in the past, implementing them in a year of high income might be a good idea.

This article gives you a few ideas for potential tax savings for 2013 income and beyond. The key is to take the time to evaluate which of these concepts, or others not mentioned in this short article, may work for you. In 2013, all physicians need to be as financially efficient as possible. DT







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So, how can you maintain that busy schedule, and stay up-to-date with the latest medical research?

Using an application that compiles research from various journals would help strengthen your searching power.

Try one of these medical journal curation apps:

JOURNAL CLUB

iPhone & Android

$2.99

Not only does this app provide one of the most exhaustive lists of top articles in medicine, Journal Club saves you time as physicians condense the information into a CliffsNotes-like setup.

DOCWISE

iPhone, iPad

FREE

Adds journals daily based on request, while alerting users as journals are uploaded. This app doesn't just provide journals; docwise also gives users the option to scan recent medical news and topics.

THE MEDICAL READER

iPhone, iPod touch, iPad

$1.99

This app does not provide access to the full-length articles, but The Medical Reader stores the most recent articles from three journals: the New England Journal of Medicine, Journal of the American Medical Association and The Lancet. You'll also have the option to save abstracts to favorites, then view offline.

READ BY QXMDREAD

iPhone, iPod touch, iPad

FREE

This app probably has the best journal library, and Read by QxMd's usefulness is matched by its user interface. Its one-tap access to full text content is nice. But Read by QxMd's curation of medical literature might be one its best features.

IMPORTANT INFORMATION ABOUT

CLOBEX® SPRAY, 0.05%

(clobetasol propionate)

BRIEF SUMMARY

This summary contains important information about CLOBEX [KLO-bex] Spray, 0.05%. It is not meant to take the place of your doctor's instructions. Read this information carefully before you start using CLOBEX Spray. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about CLOBEX Spray. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS CLOBEX SPRAY?

CLOBEX Spray is a prescription corticosteroid medicine used to treat adults with moderate to severe plaque psoriasis that affects up to 20% of the body's skin surface. CLOBEX Spray is for use on the skin only (topical).

- CLOBEX Spray should only be used for the shortest amount of time needed to treat your plaque psoriasis.
- Do not use more than 26 sprays for each application or more than 52 sprays in 1 day.
- You should not apply more than 59 mL (2 fluid ounces) of CLOBEX Spray to your skin in 1 week.

You should not use CLOBEX SPRAY:

- on your face, under arms (armpits), or groin area
- if you have thinning of the skin (atrophy) at the treatment site
- to treat rosacea or perioral dermatitis (a rash around the mouth)

WHO IS CLOBEX SPRAY FOR?

CLOBEX Spray is for use in adults 18 years of age or older.

Use in people under 18 years of age is not recommended because safety has not been established and because numerically high rates of HPA axis suppression were seen with other clobetasol propionate topical formulations.

Do not use CLOBEX Spray for a condition for which it was not prescribed. Do not give CLOBEX Spray to other people, even if they have the same symptoms you have. It may harm them.

WHAT SHOULD I TELL MY DOCTOR BEFORE USING CLOBEX SPRAY?

Before you use CLOBEX SPRAY, tell your doctor if you:

- have a skin infection. You may need medicine to treat the skin infection before you use CLOBEX Spray.
- plan to have surgery.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if CLOBEX Spray will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if CLOBEX Spray passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use CLOBEX Spray.

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 take other corticosteroid medicines by mouth or use other products on your skin that contain corticosteroids. Ask your doctor or pharmacists if you are not sure.

WHAT SHOULD I AVOID WHILE USING CLOBEX SPRAY?

- **CLOBEX Spray is flammable.** Avoid heat, flames or smoking while applying CLOBEX Spray to your skin.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF CLOBEX SPRAY?

CLOBEX SPRAY can pass through your skin. Too much CLOBEX Spray passing through your skin can shut down your adrenal glands. Your doctor may need to do blood tests to check for adrenal gland function while you are on CLOBEX Spray.

The most common side effects with CLOBEX Spray include:

- burning at treated site
- upper respiratory tract infection
- runny nose
- sore throat
- dry, itchy, and reddened skin

If you go to another doctor for illness, injury or surgery, tell that doctor you are using CLOBEX Spray. Tell your doctor if you have any side effect that bothers you or doesn't go away. These are not all of the possible side effects of CLOBEX Spray. 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 CLOBEX SPRAY?

- Use CLOBEX Spray exactly as your doctor tells you to use it.
- Your doctor should tell you how much CLOBEX Spray to use and when to apply it.
- CLOBEX Spray is for use on skin only. Do not get CLOBEX Spray near or in your eyes, mouth, or vagina.
- You should not use CLOBEX Spray on your face, under arms (armpits), or groin area.
- Apply CLOBEX Spray 2 times each day.
- Apply only enough CLOBEX Spray to cover the affected skin area. Rub in gently.
- Wash your hands after using CLOBEX Spray.
- Throw away any unused CLOBEX Spray.
- Do not bandage or cover your treated areas unless your doctor tells you to.
- Tell your doctor if your skin condition is not getting better after 2 weeks of using CLOBEX Spray.Your doctor may tell you to apply CLOBEX Spray to certain areas of your skin for up to 2 more weeks if needed. You should not use CLOBEX Spray for more than 4 weeks unless your doctor tells you to. This can increase your risk of serious side effects.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT CLOBEX SPRAY?

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

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
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2004953-0111-BS

GALDERMA
Committed to the future of dermatology

Clobex®
(clobetasol propionate) Spray, 0.05%

References: 1. Clobex® Spray Prescribing Information. September 2012. Galderma Laboratories, L.P. **2.** Data on file. Galderma Laboratories, L.P.

For the treatment of moderate to severe plaque psoriasis for up to 4 weeks in adults

THINK *FAST*

Early results with Clobex® (clobetasol propionate) Spray, 0.05%

- An average of 80% of patients were clear or almost clear at week 4 in 2 pivotal phase III trials with CLOBEX® Spray (n=120)[1]*
- At week 1, 74% of patients showed improvement in Overall Disease Severity (ODS) by at least one grade[2]
- The most common adverse reactions (>2%) were burning, pruritus, nasopharyngitis and upper respiratory tract infection[1]*

*From 2 randomized, vehicle-controlled clinical trials that were identically designed to assess the efficacy and safety of CLOBEX® Spray (n=120) or vehicle spray (n=120) in patients with moderate to severe plaque psoriasis for up to 4 weeks. Patients were evaluated on their ODS.[1]

Important Safety Information for Clobex® Spray
Indication: CLOBEX® Spray, 0.05% is indicated for the topical treatment of moderate to severe plaque psoriasis affecting up to 20% body surface area (BSA) in adults 18 years of age or older. **Adverse Events:** In controlled clinical studies, the most common adverse reactions (> 2%) were burning, pruritus, nasopharyngitis and upper respiratory tract infection. Local adverse reactions may occur more frequently with the use of occlusive dressings. **Warnings/Precautions:** Clobetasol propionate has been shown to suppress the HPA axis at the lowest doses tested. Treatment should be limited to 4 weeks. The total dosage should not exceed 50 g (59 mL or 2 fl oz) per week. Do not use more than 26 sprays for each application or more than 52 sprays in 1 day.

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 adjacent page for brief summary of Prescribing Information.

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Clobex®
(clobetasol propionate) Spray, 0.05%
UNLEASH THE POWER