ACO PARTICIPATION

Whether to join one and how to choose a good match

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THE SKIN BARRIER OF ROSEAE PATIENTS IS COMPROMISED

CHOOSE THE (ONE) VEHICLE THAT PROTECTS WHILE IT PERFORMS¹,²*

METROGEL® (metronidazole) Gel, 1% FEATURES A SOPHISTICATED FORMULATION FOR POWERFUL EFFICACY AND TOLERABILITY

• The only ONE with niacinamide that helps protect the skin barrier and facilitate drug delivery¹,³

• ONE with powerful QD efficacy: 71% median reduction in inflammatory lesion count at week 10 (P=.0005 vs vehicle)²

• ONE with a tolerable formulation: mild-to-moderate local skin irritation (ie, dryness and scaling) reported in clinical trials²

• Now the only ONE in a pump

• Rosacea sufferers surveyed prefer the pump over the tube (69% vs 31%; N=207)²†

MetroGel® (metronidazole) Gel, 1% is indicated for the topical treatment of inflammatory lesions of rosacea.

Important Safety Information

The following adverse experiences have been reported with the topical use of metronidazole: nasopharyngitis, upper respiratory tract infections and headache. Patients may also experience local burning, skin irritation, dryness and transient redness. Although rare, patients may also experience metallic taste, numbness or paresthesia of the extremities and nausea with use of MetroGel® 1%, and peripheral neuropathy has been reported with use of metronidazole. MetroGel® 1% therapy should be reevaluated if these symptoms occur. Caution should be used when prescribing metronidazole products for patients with blood dyscrasia, and patients using blood thinning agents such as coumarin or warfarin may experience prolonged prothrombin times. MetroGel® 1% is contraindicated in patients with a history of hypersensitivity to metronidazole or any other ingredient in the formulation.

Please see next page for brief summary of full Prescribing Information.

*MetroGel® 1% does not further damage the already compromised skin barrier of rosacea patients.
† Claims are based on a Consumer Packaging Preference Study of 207 physician-diagnosed, male and female rosacea patients aged 25 to 65 years. Patients were asked to complete a self-administered Internet survey following video presentations highlighting the steps involved when applying medication from a pump and a tube.

METROGEL® (metronidazole) Gel, 1% Rx Only
For topical use only.
Not for oral, ophthalmic or intravaginal use.
Talk to your doctor or pharmacist to learn more about METROGEL. You can also learn more at www.metrogel.com.

BRIEF SUMMARY
INDICATIONS AND USAGE
METROGEL® (metronidazole) Gel, 1% is a nitroimidazole indicated for the topical treatment of inflammatory lesions of rosacea.

CONTRAINDICATIONS
METROGEL® is contraindicated in those patients with a history of hypersensitivity to metronidazole or to any other ingredient in this formulation.

WARNINGS AND PRECAUTIONS
• Peripheral neuropathy, characterized by numbness or paresthesia of an extremity has been reported in patients treated with systemic metronidazole. Although not evident in clinical trials for topical metronidazole, peripheral neuropathy has been reported with the post approval use. The appearance of abnormal neurologic signs should prompt immediate reevaluation of METROGEL therapy.
• Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of, blood dyscrasia.
• If dermatitis occurs, patients may need to discontinue use.
• Topical metronidazole has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided.

ADVERSE REACTIONS
Most common adverse reactions (incidence >2%) are nasopharyngitis, upper respiratory tract infection, and headache.

In a controlled clinical trial, 557 patients used metronidazole gel, 1% and 189 patients used the gel vehicle once daily for up to 10 weeks. The following table summarizes selected adverse reactions that occurred at a rate of ≥1%:

Table 1: Adverse Reactions That Occurred at a Rate of ≥1%

<table>
<thead>
<tr>
<th>System Organ Class/Preferred term</th>
<th>Metronidazole Gel, 1%</th>
<th>Gel Vehicle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with at least one AE</td>
<td>N=557</td>
<td>N=189</td>
</tr>
<tr>
<td>Number (% of Patients)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>186 (33.4)</td>
<td>51 (27.0)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>17 (3.1)</td>
<td>8 (4.2)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>8 (1.5)</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>14 (2.5)</td>
<td>4 (2.1)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>6 (1.1)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Vaginal mycotic</td>
<td>1 (0.2)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>18 (3.4)</td>
<td>5 (2.6)</td>
</tr>
<tr>
<td>Back pain</td>
<td>3 (0.5)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>4 (0.7)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Basal cell carcinoma</td>
<td>1 (0.2)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>16 (2.9)</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>12 (2.2)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>22 (3.9)</td>
<td>5 (2.6)</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>6 (1.1)</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>36 (6.5)</td>
<td>12 (6.3)</td>
</tr>
<tr>
<td>Contact dermatitis</td>
<td>7 (1.3)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Dry Skin</td>
<td>6 (1.1)</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>8 (1.4)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>6 (1.1)</td>
<td>1 (0.5)</td>
</tr>
</tbody>
</table>

Table 2: Local Cutaneous Signs and Symptoms of Irritation That Were Worse Than Baseline

<table>
<thead>
<tr>
<th>Sign/Symptom</th>
<th>Metronidazole Gel, 1%</th>
<th>Gel Vehicle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dryness</td>
<td>N=344</td>
<td>N=184</td>
</tr>
<tr>
<td>Mild</td>
<td>93 (17.1)</td>
<td>41 (22.3)</td>
</tr>
<tr>
<td>Moderate</td>
<td>42 (7.7)</td>
<td>20 (10.5)</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (0.6)</td>
<td>2 (1.1)</td>
</tr>
<tr>
<td>Scaling</td>
<td>134 (24.6)</td>
<td>60 (32.6)</td>
</tr>
<tr>
<td>Mild</td>
<td>88 (16.2)</td>
<td>22 (17.4)</td>
</tr>
<tr>
<td>Moderate</td>
<td>43 (7.9)</td>
<td>27 (14.7)</td>
</tr>
<tr>
<td>Severe</td>
<td>3 (0.6)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>86 (15.8)</td>
<td>45 (19.8)</td>
</tr>
<tr>
<td>Mild</td>
<td>53 (9.7)</td>
<td>21 (11.4)</td>
</tr>
<tr>
<td>Moderate</td>
<td>27 (5.0)</td>
<td>13 (7.1)</td>
</tr>
<tr>
<td>Severe</td>
<td>6 (1.1)</td>
<td>3 (1.6)</td>
</tr>
<tr>
<td>Stinging/burning</td>
<td>56 (10.3)</td>
<td>28 (15.2)</td>
</tr>
<tr>
<td>Mild</td>
<td>39 (7.2)</td>
<td>18 (9.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 (1.3)</td>
<td>9 (4.9)</td>
</tr>
<tr>
<td>Severe</td>
<td>10 (1.8)</td>
<td>1 (0.5)</td>
</tr>
</tbody>
</table>

The following additional adverse experiences have been reported with the topical use of metronidazole: skin irritation, transient redness, metallic taste, tingling or numbness of extremities, and nausea.

Post Marketing Experience
The following adverse reaction has been identified during post approval use of topical metronidazole: peripheral neuropathy. Because this reaction is reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate the frequency or establish a causal relationship to drug exposure.

DRUG INTERACTIONS
Oral metronidazole has been reported to potentiate the antiocoagulant effect of coumarin and warfarin, resulting in a prolongation of prothrombin time. Drug interactions should be kept in mind when METROGEL is prescribed for patients who are receiving anticoagulant treatment, although they are less likely to occur with topical metronidazole administration because of low absorption.

USE IN SPECIFIC POPULATIONS
Pregnancy: Teratogenic Effects: Pregnancy Category B.
There are no adequate and well-controlled studies with the use of METROGEL in pregnant women. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. No fetotoxicity was observed after oral administration of metronidazole in rats or mice at 200 and 20 times, respectively, the expected clinical dose. However, oral metronidazole has shown carcinogenic activity in rodents. Because animal reproduction studies are not always predictive of human response, METROGEL should be used during pregnancy only if clearly needed.

Nursing Mothers
After oral administration, metronidazole is secreted in breast milk in concentrations similar to those found in the plasma. Even though blood levels taken after topical metronidazole application are significantly lower than those achieved after oral metronidazole a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and the risk to the infant.

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

Geriatric Use
Sixty-six subjects aged 65 years and older were treated with metronidazole gel, 1% in the clinical study. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic, oral administration in mice and rats, but not in studies involving hamsters. In several long-term studies in mice, oral doses of approximately 225 mg/kg/day or greater (approximately 37 times the human topical dose on a mg/m2 basis) were associated with an increase in pulmonary tumors and lymphomas. Several long-term oral studies in the rat have shown statistically significant increases in mammary and hepatic tumors at doses >885 mg/m2/day (144 times the human dose).

Metronidazole has shown evidence of mutagenic activity in several in vitro bacterial assay systems. In addition, a dose-related increase in the frequency of micronuclei was observed in mice after intraperitoneal injections. An increase in chromosomal aberrations in peripheral blood lymphocytes was reported in patients with Crohn's disease who were treated with 200 to 1200 mg/day of metronidazole for 1 to 8 months. However, in another study, no increase in chromosomal aberrations in circulating lymphocytes was observed in patients with Crohn's disease treated with the drug for 8 months.

In one published study, using albino hairless mice, intraperitoneal administration of metronidazole at a dose of 45 mg/kg/day (approximately 7 times the human topical dose on a mg/m2 basis) was associated with an increase in ultraviolet radiation-induced skin carcinogenesis. Neither dermal carcinogenicity nor photocarcinogenicity studies have been performed with METROGEL or any marketed metronidazole formulations.

PATIENT COUNSELING INFORMATION
Patients using METROGEL should receive the following information and instructions:
1. This medication is to be used as directed.
2. It is for external use only.
3. Avoid contact with the eyes.
4. Do not use until after affected area(s) have been cleansed before applying METROGEL.
5. This medication should not be used for any condition other than that for which it is prescribed.
7. Patients should report any adverse reaction to their physicians.

Marketed by: Manufactured by:
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DEAR READERS,

The winds of March remind me that change is blowing in.

The days grow longer, spring seems possible, and the weather hints at a mildness to come. And while the change from winter weather can be positive (i.e., no more threat of needing to shovel in the mornings), in the rest of life, change often carries with it a certain amount of anxiety. I am struck that so many of our articles in DW this month deal with upcoming changes in dermatology too. Hopefully, understanding more about these issues will help everyone be as prepared as possible and demystify the future just a bit.

At my weekly dermatology conference I’ve lately been hearing physicians saying that private practice is breathing its last gasps. If this were a play, then we could all imagine feeling the chill winds of ACOs entering stage left as the uncomplicated world of private practice is blown off the stage. Is this the case? Two of our articles this month sleuth out the state of affairs for accountable care organizations. Fact is separated from fiction in our legal column as Daniel Shay, JD, write about the probable numbers of ACOs expected throughout the country and address the question of whether participation for all dermatologists is inevitable. Ruth Carol, one of our contributing writers, writes about strategies for choosing an ACO if you decide to join one. Both articles review information you will want to be up on, so do yourself a favor and read them.

For those of you paying attention to the national elections, learning more about the status of the Massachusetts health reform is also a must-read. Health reform is certainly going to remain a front-stage issue for all of our candidates. I thought you’d find it interesting to review the experience of our colleagues in Massachusetts over these past several years. As is often the case it seems that the winds have blown both good and bad. For example, must be nice to not need to try to figure out how to care for those without health insurance; however, falling payments and fewer payers are not so good. Take a look and see how the specialists in the state grade the reforms.

And then there are two articles about new changes that are arriving which herald much promise for dermatology. Be sure to read our piece on the exciting new skin cancer therapies as well as the interview with Emmanuella Guenova, MD, on a potential new understanding of pyoderma gangrenosum. Sort of like the warmer weather...hard to not be excited to see these new developments coming our way. Maybe we should all ask this month’s Balance in Practice contributor, Naomi Lawrence, MD, to sing about it when we see her in San Diego! And by the way, please do stop me in the halls of the convention center and let me know your thoughts on DW. We value your comments and appreciate your suggestions.

Enjoy your reading.

ABBY S. VAN VOORHEES, MD, PHYSICIAN EDITOR
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She’s paid 45% of her bill after 90 days.

Wouldn’t you rather have 100% after 2 days?

Your hard-earned reputation means patients will wait months for your dermatology services. You shouldn’t have to wait months for payment. With CareCredit® Patient Payment Plans, part of GE Capital, you receive your money in just 2 business days, even if the patient delays payment or never pays. You reduce your A/R, improve your cash flow, and eliminate the time and money spent on collections. Your patients will also like the convenience CareCredit provides. They can pay over time in easy monthly payments that fit their budget. Plus, they can keep using it for additional or follow-up treatment you’ve recommended. It’s an ideal way to pay for cosmetic procedures or procedures not covered by their insurance. It’s a win-win for your practice and your patients.

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I’ve been notified that I am going to be audited. What should I do?
Don’t panic. Don’t change any documentation. Be honest and explain why you coded visits as you did. To prepare for the audit, access the American Academy of Dermatology Audit Survival Tool Kit, which can be found online at www.aad.org/member-tools-and-benefits/practice-management-resources/coding-and-reimbursement.

The most common audits are: Recovery Audit Contractor (RAC) audits, Comprehensive Error Rate Testing (CERT) audits, and the Medical Contractor Review (MR) audits. RACs are becoming increasingly common and are covered in detail in the AAD Audit Survival Toolkit.

The best way to survive an audit is to ensure that your documentation is well-organized and you have an effective compliance plan in place. Common reasons to be audited include:

• You are an outlier in your billing practices.
• A disgruntled employee has reported suspected irregularities in your billing practices.
• A recent ex-spouse has done the same.

It is to your benefit to have an effective compliance plan in place and to do internal audits. The compliance plan should require at least 10-15 medical records to be reviewed every year for established physicians and 10-15 records to be reviewed every six months for new physicians. The AAD toolkit provides an audit tool for you to use. My advice is to audit records that have not yet been billed to Medicare, so any mistakes found can easily be corrected before the bill goes out. It is helpful to have a stated policy as to when you use 1995 and when you use 1997 documentation criteria. (CMS defines these criteria at www.cms.gov/medicare/patient-care/claims-reimbursement/criteria.asp.) This will make it easier for the auditor to understand how you determined the appropriate level of service for each visit.

Common reasons why practices do poorly in an audit include the following:

ILLEGIBLE OR UNSIGNED MEDICAL RECORDS
Legible signatures are as important as legible clinic notes. Ancillary staff notes should be clearly identified, signed and dated as well. If your signature is a bit messy, but clearly recognizable, I recommend that you maintain a log with your signature and that of all ancillary staff clearly identified so that an auditor can match the signature to that recorded in the record.

ADDITIONAL DOCUMENTATION REQUESTS FROM THE AUDITOR
It is best to log the receipt of each request, and confirm the response to each of these requests. Provide whatever additional information might be helpful. In some instances, explanation of custom and habit
may prove beneficial.

POORLY DOCUMENTED COMPONENTS OF THE E/M SERVICE
For new patients, all three key components are needed to determine the correct code selection: (1) history, (2) physical, and (3) medical decision making. For established patients, 2 of the 3 are needed. Make sure the elements are appropriate to the chief complaint. For the physical exam, a notation of “normal” is acceptable for uninvolved areas that are medically appropriate to examine. For dermatology visits, the number of diagnoses and risk generally determine the level of medical decision making.

REVIEW OF SYSTEMS (ROS)
Some carriers allow auditors to “double dip” in the history of present illness to find elements of a review of systems. While this can be helpful, it is generally best to template your notes so the ROS can easily be found. If a ROS cannot be obtained, document why. Make sure one relates to the skin, that you count organ systems instead of bullets, and that all systems asked are appropriate to the presenting complaint.

TIME USED TO DETERMINE THE E/M SERVICE BUT NOT DOCUMENTED
Document the total time you spent with the patient and the time that was face-to-face counseling (must be >50 percent).

MISUSE OF MODIFIER 25
In order to justify modifier 25, there must be documentation of significant, separately identifiable E/M services above those included in the procedure. \textit{dw}
FDA approves drug for advanced BCC

The Food and Drug Administration approved vismodegib, the first drug approved for treatment of advanced basal cell carcinoma (BCC), on Jan. 30. The drug, being marketed as Erivedge and developed by Genentech, targets the hedgehog pathway. It was approved under the FDA’s expedited review program; the approval included a boxed warning noting that vismodegib has the potential to cause fetal death or severe birth defects and requires verification of pregnancy status prior to treatment.

In announcing vismodegib’s approval, Richard Pazdur, MD, director of the Office of Oncology Drug Products in the FDA’s Center for Drug Evaluation and Research, said, “Our understanding of molecular pathways involved in cancer, such as the hedgehog pathway, has enabled the development of targeted drugs for specific diseases. This approach is becoming more common and will potentially allow cancer drugs to be developed more quickly. This is important for patients who will have access to more effective therapies with potentially fewer side effects.”

Vismodegib was approved based on the results of a multi-center study of 96 patients with locally advanced or metastatic BCC. In the trial, 30 percent of patients with metastatic disease experienced a partial response, while 43 percent of patients with locally advanced disease experienced a complete or partial response.

For more information about the trial and access to prescribing information, visit www.fda.gov/Drugs/InformationOnDrugs/approvedDrugs/ucm289571.htm. – RICHARD NELSON

Proposed transparency rules would burden physicians

MANUFACTURERS OF DRUGS, DEVICES, BIOLOGICS, OR MEDICAL SUPPLIES would be required to report certain payments or transfers of value provided to physicians or teaching hospitals under a proposed rule announced by the Centers for Medicare and Medicaid Services in December. The rule, which implements the Physician Payment Sunshine Act provisions of the health system reform law, would require manufacturers to report a transfer of anything with a value of $10 or more, including cash equivalents, in-kind items or services, or stocks.

In comments submitted to CMS, the American Academy of Dermatology Association noted its concerns with the review process established by the proposed rule and the overall burden it would create for physicians. The AADA suggested that the final rule should allow for pre-submission review of reports by the physicians named in those reports by manufacturers, noting that allowing this would improve the accuracy of the information submitted to CMS and prevent disputes during the 45-day review period called for by the proposed rule. The AADA also suggested that the final rule should allow third-party review of submissions so CME providers and medical associations can scrutinize them on behalf of members and presenters. Finally, the AADA noted that while the rule places the burden for reporting on manufacturers, reviewing the reports submitted by manufacturers will require physicians to keep an accurate record of all transfers valued at more than $10, creating an additional record-keeping burden for them.

Comments were due Feb. 17; a final rule is expected later this year. – RICHARD NELSON

CORRECTION

AN ARTICLE IN THE FEBRUARY ISSUE OF DERMATOLOGY WORLD, “Empty promises,” (p. 26), misstated the timeline for phasing out the New Jersey cosmetic procedure tax. The tax will drop to 4 percent on or after July 1, 2012 but before July 1, 2013; drop to 2 percent on or after July 1, 2013 but before July 1, 2014; and be phased out entirely on July 1, 2014.
For the first-line treatment of inflammatory and comedonal acne

Prescribe the

BRANDED TOPICAL ACNE PRODUCT AMONG DERMATOLOGISTS®

NOW AVAILABLE IN A PUMP!

The only, once-daily adapalene/benzoyl peroxide combination—in a patient-preferred PUMP.

- 79% of acne patients preferred the PUMP over the tube
- 92% of acne patients reported satisfaction with the PUMP

Measured dose for consistent delivery.

*Survey of 251 patients 12 to 35 years of age who completed a randomized study of Epiduo® Gel tubes in pump after 1 week of treatment with each dispenser.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
Please see brief summary of Prescribing Information on next page.
**EPIDUO® (adapalene and benzoyl peroxide) Gel 0.1% / 2.5%**

For Topical Use Only
Not For Ophthalmic, Oral, or Intravaginal Use.

**BRIEF SUMMARY**

**INDICATIONS AND USAGE**
EPIDUO Gel is a combination of adapalene, a retinoid, and benzoyl peroxide, and is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

**CONTRAINDICATIONS**
None.

**WARNINGS AND PRECAUTIONS**
UltraViolet Light and Environmental Exposure: Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, and stinging/burning may occur with use of EPIDUO Gel.

**ADVERSE REACTIONS**
Observed local adverse reactions in patients treated with EPIDUO Gel were erythema, scaling, dryness, stinging, and burning. Other most commonly reported adverse events (≥1%) in patients treated with EPIDUO Gel were dry skin, contact dermatitis, application site burning, application site irritation, skin irritation.

**DRUG INTERACTIONS**
Exercise caution in using preparations containing sulfur, resorcinol, or salicylic acid, medicated or abrasive soaps and cleansers and products with high concentrations of alcohol or astringents in combination with EPIDUO Gel. Concomitant use of topical products with a strong drying effect can increase irritation. Use with caution.

**Pregnancy**

Pregnancy Category C. There are no well-controlled trials in pregnant women treated with EPIDUO Gel. Animal reproduction studies have not been conducted with the combination gel or benzoyl peroxide. Furthermore, such studies are not always predictive of human response. Therefore, EPIDUO Gel should be used during pregnancy only if the potential benefits justify the risk to the fetus.

No teratogenic effects were observed in rats treated with oral doses of 0.15 to 5.0 mg adapalene/kg/day, up to 25 times (mg/m²/day) the maximum recommended human dose (MRHD) of 2 grams of EPIDUO Gel. However, teratogenic changes were observed in rats and rabbits when treated with oral doses of ≥25 mg adapalene/kg/day (2-3× mg/m²/day) in the MRHD of 2 grams of EPIDUO Gel. No teratogenic effects were observed in rabbits at doses of 5-40 mg adapalene/kg/day (25-3× mg/m²/day). The MRHD exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits.

**Nursing Mothers**

It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of EPIDUO Gel. Because many drugs are excreted in human milk, caution should be exercised when EPIDUO Gel is administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness of EPIDUO Gel in pediatric patients under the age of 12 have not been established.

**Geriatric Use**

Clinical studies of EPIDUO Gel did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
No carcinogenicity, photocarcinogenicity, genotoxicity, or fertility studies were conducted with EPIDUO Gel.

Carcinogenicity studies with adapalene have been conducted in mice at topical doses of 0.4, 1.3, and 4.0 mg/kg/day (1.2, 3.9, and 12 mg/m²/day), and in rats at oral doses of 0.15, 0.5, and 1.5 mg/kg/day (0.9, 3.0, and 8.0 mg/m²/day). In terms of body surface area, the highest dose levels are 9.8 (mice) and 7.4 times (rats) the MRHD of 2 grams of EPIDUO Gel. In the rat study, an increased incidence of benign and malignant phaeochromocytomas in the adrenal medulla of male rats was observed. No significant increase in tumor formation was observed in rodents topically treated with 15-25% benzoyl peroxide carbopol gel (6-10 times the concentration of benzoyl peroxide in EPIDUO Gel) for two years. Rats received maximum daily applications of 158 (males) and 205 (females) mg benzoyl peroxide/kg. In terms of body surface area, these levels are 27-40 times the MRHD. Similar results were obtained in mice topically treated with 25% benzoyl peroxide carbopol gel for 56 weeks followed by intermittent treatment with 15% benzoyl peroxide carbopol gel for 2 of the 2 years study period, and in mice topically treated with 5% benzoyl peroxide carbopol gel for two years.

The role of benzoyl peroxide as a tumor promoter has been well established in several animal species. However, the significance of this finding in humans is unknown.

In a photocarcinogenicity study conducted with 5% benzoyl peroxide carbopol gel, no increase in UV-induced tumor formation was observed in hairless mice topically treated for 40 weeks.

No photocarcinogenicity studies were conducted with adapalene. However, animal studies have shown an increased tumorigenic risk with the use of pharmacologically similar drugs (e.g., retinoids) when exposed to UV irradiation in the laboratory or sunlight. Although the significance of these findings to humans is not clear, patients should be advised to avoid or minimize exposure to either sunlight or artificial irradiation sources.

Adapalene did not exhibit mutagenic or genotoxic effects in vitro (Ames test, Chinese hamster ovary cell assay, mouse lymphoma TK assay) or in vivo (mouse micronucleus test).

Bacterial mutagenicity assays (Ames test) with benzoyl peroxide has provided mixed results, mutagenic potential was observed in a few but not in a majority of investigations. Benzoyl peroxide has been shown to produce single-strand DNA breaks in human bronchial epithelial and mouse epidermal cells, it has caused DNA-protein cross-links in the human cells, and has also induced a dose-dependent increase in sister chromatid exchanges in Chinese hamster ovary cells.

In rat oral studies, 20 mg adapalene/kg/day (120 mg/m²/day; 98 times the MRHD based on mg/m²/day comparison) did not affect the reproductive performance and fertility of F0 males and females, or growth, development and reproductive function of F1 offspring.

No fertility studies were conducted with benzoyl peroxide.

**PATIENT COUNSELING INFORMATION**

- Advise patients to cleanse the area to be treated with a mild or soapless cleanser; pat dry. Apply EPIDUO Gel as a thin layer, avoiding the eyes, lips and mucous membranes.

- Advise patients not to use more than the recommended amount and not to apply more than once daily as this will not produce faster results, but may increase irritation.

- EPIDUO Gel may cause irritation such as erythema, scaling, dryness, stinging or burning.

- Advise patients to minimize exposure to sunlight, including sunlamps. Recommend the use of sunscreen products and protective apparel, (e.g., hat) when exposure cannot be avoided.

- EPIDUO Gel may bleach hair and colored fabric.

**Manufactured by:**

GALDERMA LABORATORIES, L.P.
Fort Worth, Texas 76117 USA

**Marketed by:**

GALDERMA LABORATORIES, L.P.
Fort Worth, Texas 76117 USA

**References:**


**FDA Approval:**

Epiduo (adapalene and benzoyl peroxide) Gel 0.1% / 2.5%

**References:**


**GALDERMA COMMITTED TO THE FUTURE OF THERAPEUTICS**

www.epiduo.com/hcp

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Is ustekinumab an effective treatment for pyoderma gangrenosum?

IN THIS MONTH’S ACTA ERUDITORUM COLUMN, Physician Editor Abby S. Van Voorhees, MD, talks with Emmanuella Guenova, MD, about her recent Archives of Dermatology article, "Interleukin 23 expression in pyoderma gangrenosum and targeted therapy with ustekinumab."

Q&A

DR. VAN VOORHEES: What previously has been known about the underlying pathogenetic and immunologic alterations in pyoderma gangrenosum (PG)?

DR. GUENOVA: Pyoderma gangrenosum is considered to be an idiopathic disease. In 25-50 percent of the patients, an underlying immunologic abnormality is currently favored given its frequent association with systemic disease with a suspected autoimmune or autoinflammatory pathogenesis.

Unfortunately, there is no currently available specific biomarker for PG, and the diagnosis is predominantly based on the clinical appearance. Pathology results alone are not sufficient but are supportive for the diagnostic process. In a recent issue of the JAD (64(5):950-954) Hadi and Lebwohl published a very comprehensive review of the literature and proposed strict diagnostic criteria for PG, based on anatomical location, clinical ulcer features, and associated disease.

DR. VAN VOORHEES: How frequently is PG associated with other systemic illnesses? Can you remind us of these various autoimmune processes?

DR. GUENOVA: Wines et al. (MedGenMed 3(3):6) and Crowson et al (J Cutan Pathol 30(2):97-107) published independently in 2001 and 2003, respectively, large reviews on this topic. According to them, approximately 15 percent of the patients with PG also have inflammatory bowel disease. Around 35 percent will present with arthritis. The percentages are far smaller for paraproteinemia, hematological malignancies, and some seldom-seen humoral and cellular immune abnormalities such as abnormal neutrophil or monocytes function. All of these diseases have been reported as associated conditions, but none of the findings have been demonstrated consistently in larger patient collectives.
and it is not clear whether there is a causal relation or whether some are detected “just by chance.”

**DR. VAN VOORHEES:** Are there different types of PG? Are there different associations with each of these various subtypes?

**DR. GUENOVA:** Today, PG can be classified into four main clinical-pathological variants: ulcerative, pustular, bullous and vegetative PG. The first description of the bullous pyoderma dates back to 1972, when Perry and Winkelmann described the case of a painful superficial dermatosis in three patients with leukemia (Arch Dermatol 106(6):901-905). Since then, other cases of pyoderma patients with associated hematological malignancies have been reported in the literature and most of them proved to have bullous type of PG.

Indeed, the more frequently present ulcerative PG is either idiopathic or associated mainly with intestinal bowel disease, while the bullous PG is considered to be the variant of PG that can be associated with hematological malignancies.

**DR. VAN VOORHEES:** Prior to your report, what therapies have been utilized in the treatment of this frustrating disorder?

**DR. GUENOVA:** In the initial stage of the disease, corticosteroids, and calcineurin inhibitors, mostly tacrolimus, are largely used as topical agents. Good results have been achieved in some patients using intravenous immunoglobulins, plasmapheresis, or clofazimine. Additionally, various systemic immunosuppressive regimens have been implemented in the treatment of pyoderma gangrenosum. These often have a serious adverse event profile. For example, high-dose systemic corticosteroids, azathioprine, methotrexate, cyclosporine, mycophenolate, methotrexate, and cyclophosphamide, infliximab, etanercept, etc., are successful in some patients, but not in general.

**DR. VAN VOORHEES:** Tell us a little about your patient. What about her ulcer made you think of using an IL-12/23 compound for treatment? Was it successful? Has it been tried in other patients with other subtypes of PG?

**DR. GUENOVA:** Our patient was a 37-year-old Caucasian woman with recalcitrant PG on the leg. First signs of the disease had started four weeks earlier and systemic treatment with prednisolone has been unsuccessful. Clinical examination revealed a growing skin ulcer with sharply demarcated bluish undermined margins on the left pretibial region. At the time of presentation, there was no sign of associated autoimmune disease, however Crohn’s disease was suspected in early childhood.

As we discussed above, unfortunately there is no predictive factor for personalized medicine, which can help choose the best treatment option with a highest likelihood of success in every individual patient with PG. That means: from all available and previously reported treatment options, we were supposed to pick one out, following the “trial and error” principle.

Indeed, some common clinical and histological clues for PG were the protagonists of our hypothesis of ustekinumab as a possible treatment option for this disease. Namely, a needle prick of the skin can elicit new lesions in PG-prone patients. This so-called “pathergy phenomenon” is regarded to be a clue for neutrophilic dermatoses, one of those being PG. Indeed, histological characteristics of PG are prominent infiltrations of neutrophils followed by hemorrhage and necrosis of the epidermis.

Ustekinumab is a monoclonal antibody, directed against the IL-12/IL-23p40 subunit. IL-23 plays a critical role in driving inflammation associated with IL-17 production and especially neutrophil recruitment. Association of the IL-23-pathway with multiple chronic inflammatory disorders was shown recently. Pyoderma gangrenosum has abundant neutrophilic infiltration, and is sometimes associated with autoinflammatory and autoimmune disorders. Hence our hypothesis, that PG might be driven by a pathogenetic mechanism similar to that of inflammatory bowel diseases or psoriasis.

Having all this in mind, we first performed translational research studies on a skin sample from our patient. Indeed, our first analyses demonstrated IL-23 dominated infiltrate in the lesion. This finding strongly encouraged us to choose ustekinumab as a next treatment option for our patient. After 14 weeks of treatment, the PG lesion had healed completely.

This exciting first data encouraged us to start an investigator-initiated trial on ustekinumab and PG. The study is still in progress, so we do not have more new data yet. As a first step, the objective of our study is to evaluate ustekinumab in the treatment of ulcerative PG. All other forms (pustular, bullous, and vegetative PG) will be excluded from the first pilot study.

We hope after completion, this study might specify a new concept for both the pathophysiology and treatment of PG, and will help us better understand the potential of ustekinumab as a therapeutic agent in human inflammatory and autoimmune disorders.

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**DR. GUENOVA** is a dermatologist in the departments of dermatology at Eberhard Karls University in Tübingen, Germany, and Harvard Skin Disease Research Center, department of dermatology, Brigham and Women’s Hospital in Boston. Her article was published in the Archives of Dermatology, 147(10):1203-1205 (October 2011). doi:10.1001/archdermatol.2011.168.
Proven effective in moderate to severe acne*. 1, 2

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Please see brief summary of prescribing information on adjacent page.

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.

*Individual results may vary.

ACANYA®
(clindamycin phosphate and benzoyl peroxide) Gel, 1.2% / 2.5%
Ready-to-Use 50g Pump

INDICATIONS AND USAGE
ACANYA Gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

The safety and efficacy of this product in the treatment of any other disorders have not been evaluated.

DOSEAGE AND ADMINISTRATION
Apply a pea-sized amount of ACANYA Gel to the face once daily. Use of ACANYA Gel beyond 12 weeks has not been evaluated.

ACANYA Gel is not for oral, ophthalmic, or intravaginal use.

CONTRAINdications
ACANYA Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.

WARNINGS AND PRECAUTIONs
Colitis
Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Diantha, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. When significant diarrhea occurs, ACANYA Gel should be discontinued.

Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of <7 days following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate toxin(s) produced by Clostridium is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Stool cultures for Clostridium difficile and stool assay for C. difficile toxin may be helpful diagnostically.

Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against C. difficile colitis.

ADVERSE REACTIONS
Clinical Studies Experience
Because clinical trials are conducted under prescribed conditions, adverse reaction rates observed in the clinical trial may not reflect the rates observed in practice. Because clinical trials are also conducted under widely varying conditions, adverse reactions observed in the clinical trials of a drug cannot always be directly compared to rates in the clinical trials of another drug. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse reactions that appear to be related to drug use and for approximating rates.

The following selected adverse reactions occurred in less than 0.2% of patients treated with ACANYA Gel: application site pain (0.1%); application site edema (0.1%); application site infection (0.1%); and application site irritation (0.3%).

During clinical trials, patients were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions increased and peaked around week 4 and continually decreased over time reaching near baseline levels by week 12. The percentage of patients that had symptoms present before treatment, the maximum value recorded during treatment, and the percent with symptoms present at week 12 are shown below.

Local Skin Reactions—Percent Patients with Symptoms Present. Combined Results from the Two Phase 3 Trials (N = 773)

<table>
<thead>
<tr>
<th></th>
<th>Before Treatment (Baseline)</th>
<th>Maximum During Treatment</th>
<th>End of Treatment (Week 12)</th>
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<tbody>
<tr>
<td></td>
<td>Mild</td>
<td>Mod*</td>
<td>Severe</td>
</tr>
<tr>
<td>Erythema</td>
<td>22</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Scaling</td>
<td>8</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Scaling with pain</td>
<td>10</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Burning</td>
<td>3</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Stinging</td>
<td>2</td>
<td>&lt;1</td>
<td>0</td>
</tr>
</tbody>
</table>

*Mod= Moderate

DRUG INTERACTIONS
Erythromycin
ACANYA Gel should not be used in combination with topical or oral erythromycin-containing products due to its clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vitro antagonism is not known.

Concomitant Topical Medications
Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.

Neuromuscular Blocking Agents
Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, ACANYA Gel should be used with caution in patients receiving such agents.

USE IN SPECIFIC POPULATIONS
Pregnancy Category C
There are no well-controlled trials in pregnant women treated with ACANYA Gel. It also is not known whether ACANYA Gel can cause fetal harm when administered to a pregnant woman. ACANYA Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal reproductive/developmental toxicity studies have not been conducted with ACANYA Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using oral doses of up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) or subcutaneous doses of up to 200 mg/kg/day (80 and 40 times amount of clindamycin in the highest recommended adult human dose based on mg/m², respectively) revealed no evidence of teratogenicity.

Nursing Mothers:
It is not known whether clindamycin is excreted in human milk after topical application of ACANYA Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to use ACANYA Gel while nursing, taking into account the importance of the drug to the mother.

Pediatric Use:
Safety and effectiveness of ACANYA Gel in pediatric patients under the age of 12 have not been evaluated. Clinical trials of ACANYA Gel included patients 12-17 years of age.

Geriatric Use
Clinical studies of ACANYA Gel did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger patients.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity, mutagenicity and impairment of fertility testing of ACANYA Gel have not been performed.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered topically twice per week for 20 weeks induced skin tumors in transgenic TG.AC mice. The clinical significance of this is unknown.

Carcinogenicity studies have been conducted in a gel formulation containing 1% clindamycin and 5% benzoyl peroxide. In a 2-year dermal carcinogenicity study in mice, treatment with the gel formulation at doses of 900, 2700, and 15000 mg/kg/day (1.8, 5.4, and 30 times amount of clindamycin and 3.6, 10.8, and 60 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ACANYA Gel based on mg/m², respectively) did not cause any increase in tumors. However, topical treatment with a different gel formulation containing 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthoma at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats. In an oral (gavage) carcinogenicity study in rats, treatment with the gel formulation at doses of 300, 900 and 3000 mg/kg/day (1.2, 3.6, and 12 times amount of clindamycin and 2.4, 7.2, and 24 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ACANYA Gel based on mg/m², respectively) for up to 97 weeks did not cause any increase in tumors. In a 52-week dermal photocarcinogenicity study in hairless mice, (40 weeks of treatment followed by 12 weeks of observation), the median time to onset of skin tumor formation decreased and the number of tumors per mouse increased relative to controls following chronic concurrent topical administration of the higher concentration benzoyl peroxide formulation (5000 and 10000 mg/kg/day, 5 days/week) and exposure to ultraviolet radiation.

Clindamycin phosphate was not genotoxic in the human lymphocyte chromosome aberration assay. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in S. typhimurium tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

Fertility studies have not been performed with ACANYA Gel or benzoyl peroxide, but fertility and mating ability have been studied with clindamycin. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g ACANYA Gel, based on mg/m²) revealed no effects on fertility or mating.

HOW SUPPLIED
ACANYA Gel is supplied as a 50 g pump (NDC 13548-132-50).

Dispensing instructions for the pharmacist
Dispense ACANYA Gel with a 10 week expiration date.

Specify "Store at room temperature up to 25°C (77°F). Do not freeze."

Storage and Handling
PHARMACIST: Prior to dispensing, store in a refrigerator, 2°C to 8°C (36°F to 46°F).

PATIENT: Store at room temperature at or below 25°C (77°F).

Protect from freezing.

Keep out of the reach of children.

Keep container tightly closed.

RX Only

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Since the passage of the Patient Protection and Affordable Care Act, 2010’s health reform law, there has been rampant physician anxiety and confusion over “accountable care” and Accountable Care Organizations (ACOs). They are not the same thing. Where dermatologists fit in this new landscape will be only a little clearer after you read this article, because most of what happens in this arena will depend heavily on local context. But there are practical steps dermatologists can take to position themselves for new developments.

First, the legislation itself does not mandate the creation of ACOs. They are not a pilot program or a demonstration. Physicians will not be required by law to participate in ACOs. The legislation offered a barely described opportunity, in Medicare, for organizations to step forward and apply to have a contract with the government to deliver a full continuum of care under Medicare. The basic idea is that some entity — whether driven by a hospital, a physician group, or some combined entity — would be able to accept Part A and Part B monies. To the extent the participants’ changes in care delivery save money, the ACO would get a portion of those savings to distribute among the participants.

WHERE DID THE IDEA COME FROM?
The idea emanated from a *Health Affairs* article in 2007, “Creating Accountable Care Organizations: The Extended Hospital Medical Staff,” which called for hospitals to be measured in part on the performance of physicians who never even attend there, the so-called “extended medical staff.” Then, Mark McClellan, MD, PhD, having recently left CMS as administrator to join a think tank, published on the *Health Affairs* blog, an article describing the ACO as a “shared savings
program.” In fact, the subtitle of the section in the legislation which creates the opportunity is referred to by that phrase.

When the legislation was enacted, no ACO existed. They were variously described as unicorns, HMOs in drag, and more. But to the extent commentators thought some health care organizations could step up to address the issues of being measured and accountable for the quality and value of care delivery, accepting both Part A and Part B dollars, the likeliest candidates were the kinds of organizations which had participated in the Medicare Group Practice Demonstration Project (MGPDP), which had all had to be organizations of at least 200 physicians. Interestingly, in that three year project, all the physician groups improved quality but only five out of 10 got any money, and only the Marshfield Clinic earned significant dollars, according to a 2009 report to Congress.

The American Medical Group Association (AMGA) was supportive of the ACO legislation assuming that its members would be best qualified to get the contracts CMS would make available. In many ways, the legislation governing ACOs mirrors major elements of the MGPDP approach. Successful contractors would have to serve at least 5,000 Medicare beneficiaries who would be assigned to them. Hospitals and physicians would be paid by Medicare on DRGs and the fee schedule, along the way, and then shared savings would be distributed at the end of three years. The entity would be accountable for quality in accordance with to-be-determined measures.

REGULATIONS

When proposed regulations were published early in 2011, they were soundly excoriated from all corners. All of the demonstration project participants stated publicly that they would refuse to participate without major changes. Under the proposed rule, ACOs would be subjected to 65 quality measures. Beneficiaries assigned to them not only would not know of such assignment, but CMS would do nothing to channel beneficiaries to their assigned ACO, because it was believed this would smack of closed managed care panels which Americans had roundly rejected in the mid-1990s. The amount of money successful ACOs could earn was too small to be worth the effort. Almost immediately CMS announced two other pathways to ACO status — through the Pioneer ACO program and another Advanced Payment ACO model. CMS has selected 32 organizations which applied to be Pioneer ACOs.

In the meantime CMS revised the regulations, eliminating some of the most controversial elements of the proposal, including lowering the number of quality measures from 65 to 33. Because of the sharing of money across providers, various aspects of the law to protect Medicare in its traditional programs would have to be waived. In particular, the Stark statute which prohibits referrals by physicians to hospitals, among others, where there is a financial relationship unless it meets an exception, and the anti-kickback statute which is similar but broader, would prevent ACOs from operating to accomplish their purpose. The Office of the Inspector General and CMS have issued guidelines regarding the waivers that will be available for ACOs. They are liberal and allow much more sharing of dollars across participants than would be allowed for traditional Medicare providers. There are also potential antitrust issues in the combinations of providers that will form ACOs, so the FTC has also published a statement of how it will approach enforcement of the antitrust laws. Finally, for not-for-profit hospitals which would want to participate, the tax exempt entity rules would be applied more liberally to permit hospitals to reward participating physicians for contributing to improved value.

Many have commented that the final interim regulations offer significant improvement over the proposed regulations. But even in its rosiest predictions when the proposed regulations were
announced, CMS anticipated that there might be 75-100 ACOs across the nation. There are more than 5,000 hospitals and more than 300,000 physicians in the United States. They will not all be in ACOs. Whether a dermatologist will have to pay attention to the Medicare ACO program depends on the market in which he or she practices. If there is one hospital in town, it employs most of the physicians, and they increasingly refer only “within the network,” then participation in an ACO may be worth considering. If dermatologists are part of large multi-specialty groups which are participating, they may find themselves confronting some of the issues the ACO regulations generate, especially those pertaining to quality measurement and potential sharing in distributions at the end of three years. But Medicare ACOs are not likely to be a major factor in most dermatology practices. That said, “accountable care” is a different story altogether.

**ACCOUNTABLE CARE**

Medicare ACOs will exist under specific legislation and regulation. Commercial payers, however, are also moving toward fostering ACOs of some kind, in varying degrees, throughout the country. (In Massachusetts there is a bill that would require ACOs throughout the state as the way health care will be delivered and paid for, but today, it is only a bill and not law.) These ACOs tend to be focused around hospital-centric entities. Sometimes larger medical groups can lead the way, but the broad continuum of care to be addressed by organizational reconfigurations is only part of the story. The more important story for dermatologists is the one about accountable care regardless of the organizational structure.

No ACO will succeed without a clear understanding of for what it is accountable. But even outside of ACOs, most physicians will have to change some aspects of their care delivery in light of the new emphasis on accountable care.

Throughout the health reform legislation and increasingly in private payer initiatives, the principle of physicians being expected to be accountable for care is proliferating. This means all physicians can expect to be measured in terms of their quality and especially the patient experience of care. Their efficiency in terms of the cost effectiveness of care is also squarely on the table as employers seek to reduce their health care costs. Together, the new emphasis on measured quality and improved efficiency defines the new paradigm of value. Commercial payers are using pay-for-performance programs as well as selected networks of high scoring physicians to motivate a shift to higher value health care.

Unbeknownst to many physicians who are hearing the drumbeat that fee for service is disappearing, in fact there is a mandatory program of accountability in the health reform law that will affect their Medicare payment. Beginning in 2013 with composite quality measures, the Medicare physician fee schedule will be subjected to a value-based purchasing modifier. Beginning in 2015, physicians’ efficiency will be measured by an episode grouper — a software package that takes fee-for-service claims data and stitches it back together into a defined episode of care around a diagnosis — for which CMS offers additional money for reporting, but beginning in 2015, those who do not report in this system will have their payments from Medicare reduced.

**WHAT SHOULD DERMATOLOGISTS DO?**

Because physicians will increasingly be measured for their quality performance, patient experience of care, and value, they should know what measurement programs currently exist in their community. If you cannot find that by relying on local resources, or if none seems to be present, then measure yourselves using good clinical practice guidelines. Survey your patients about their experience of care. Study the data and analyze the results. (See sidebar for information on tools the Academy offers to help members with this task.)

Physician practices that will succeed in the new environment will undoubtedly be those that are clinically integrated, even within their own practices. These will be “Physicians working together systematically, with or without other organizations and professionals, to improve their collective ability to deliver high quality, safe, and valued care to their patients and communities.” There are at least 17 attributes of a clinically integrated entity, including a physician practice. A good exercise would be to use a new self-assessment tool, available at www.uft-a.com/CISAT.pdf, to figure out where your practice is on the continuum of integration for value, and then start to plan how to improve your performance.

ACOs will unfold over the next few years and only some dermatologists will be involved. Being accountable for your care, however, will be increasingly inescapable. 

*dw*
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Learn how you could start saving valuable time with EMA by scheduling a demonstration today. For more information visit www.modernizingmedicine.com or stop by booth #311 at the AAD Conference.
Note perfect

EACH MONTH DERMATOLOGY WORLD tackles issues “in Practice” for dermatologists. This month dermatologist Naomi Lawrence, MD, writes about how she makes time in her schedule for singing, and how doing so makes her a better doctor.

From a very early age, I’ve loved singing. I started singing with my sister at Sunday Mass on the Tulane campus, where my father was a professor. After a while, people were coming out to hear us sing, and it’s from there that my passion for singing and performing began. I was around eight or nine then, and singing has been a big part of my life ever since.

As I grew, my sister and I began singing at weddings, parties, and musical theater, and these moments are just as much a part of my development as medicine has been. During medical school, I continued to train in singing, and even did regular recitals. But with internship, residency, and eventually kids, I finally had to take time off from rehearsing and performing. Over the ensuing years, life became increasingly full with my academic Mohs and cosmetic practice, and becoming a mother of three teenage boys. As a person who wants to be very involved in my family’s lives, that’s meant coming home as early as I can, making dinner, and having family time. I don’t keep any household staff, because I want to be hands-on. So time has long been at a premium.

MAKING TIME

About 10 years ago, I decided to begin incorporating singing back into my life again, and found a professor at Rutgers who agreed to train me. As my husband and I have always encouraged the three boys to participate in sports and other activities, I realized that to make this possible I’d need to be very adaptable in my training. So for example, once I know the song I’ll be working on for the week, I find videos and performance versions of the song, and put those on my MP3 player. I’ll watch or listen to a performance while I’m working out or during a couple minutes of downtime between driving the boys around town. It really helped me to
hear someone else's interpretation of a piece and build from there so that I could learn the music more quickly. I also tape every one of my lessons so that I can go back to them when I'm practicing, even in the car.

Twice a year, the professor I train under will ask 16 or so of her students to participate in a spring or fall recital... this is something that I always look forward to despite the effort required. I get tremendous satisfaction from performing and giving these recitals my best effort. Having trained for many years, it's also great to see people of all ages singing the songs that I was learning when I was at their level. It takes dedication to embrace your avocation again while still fulfilling all your responsibilities, but with reasonable expectations and determination to incorporate it into your life, it's not just possible but rewarding for me to balance career, family, and music.

GOING PUBLIC
In 2010, I gave an hour long recital at a meeting of the American Dermatologic Association, performing for my colleagues at the Ritz Carlton in New York. It was a rewarding experience seeing the combination of a career I'm passionate about with my lifelong love of music and performance. A few years ago the Department of Medicine at my university had a Medicine and Art series and I was invited to sing an aria in front of the entire department of medicine at Cooper, which revealed my semi-secret hobby to a lot of my colleagues and patients.

As a result of these performances word has gotten out, and both colleagues and patients seem to have learned of my beloved hobby. This has had pluses and minuses. On one hand, you want patients to think of you first and foremost as their doctor, and a lot of them may not have considered that we as doctors have a life and hobbies outside the office. On the other some of my patients occasionally bring it up, and seem to enjoy that I have an interest that goes beyond medicine. I don't think I'll be looping video of my performances in the office any time soon, but it's nice that they recognize my life outside the office.

My observation has been that a lot of artistically inclined people end up in dermatology. We're visual people, and naturally migrate to this visual specialty. We use all of our senses, and there are a lot of aesthetic considerations in our day-to-day. So it's probably not surprising that so many of us are musically inclined, whether it's playing the piano, singing, or performing violin — it all comes down to skillful appreciation of and interaction with aesthetics.

Further, I believe that dermatology is a career that allows its practitioners to strike a healthier work/life balance. I have more control over my day than some of my colleagues in other specialties. I can come home at a regular time, make dinner for my family, and still have a few hours a week to sing and rehearse before getting back to my career.

MAKING IT WORK
Still, you have to accept that you can’t do everything. That is the number one rule in my mind. Set your priorities and do your best, but don’t be upset with yourself when you feel that you’re always compromising somewhat. I often feel that I am leaving something undone at work, and just barely getting to pick up my kids. My house is not always as clean as I would like it to be. My big regret for my music is that I feel that I need to stick to recitals rather than performing in shows. I know that a rehearsal schedule would be a lot less flexible to juggle. It seems to me that those of us drawn to medicine are often perfectionists. Making this balance work requires letting that go a bit, and accepting that everything is not going to be perfect.

Things that take me out of my comfort zone help make me a better physician because they allow me to be more well-rounded. And things that humanize me make me a better physician.

Singing provides a physical, mental, and emotional challenge that gives me better balance as a person. dw
ACO PARTICIPATION

Whether to join one and how to choose a good match

BY RUTH CAROL, CONTRIBUTING WRITER
The final rule regarding accountable care organizations (ACOs) may be published, but the final word on how dermatologists can best participate in these new entities has yet to be written.

ACOs are patient-centric entities that create incentives for health care providers to coordinate care, in this case for Medicare beneficiaries, across settings. ACOs that lower costs while meeting quality measures will be financially rewarded through the Shared Savings Program. Medicare could potentially save up to $960 million the first three years, which is the length of the ACO agreements. The final rule released by the Centers for Medicare and Medicaid Services (CMS) on Oct. 20, 2011 has made it easier and less risky for physicians to participate in an ACO than it would have been under the proposed rule released last summer.

“All of the changes, by and large, were designed to make this program more attractive,” said George Roman, senior director of health policy for the Alexandria, Va.-based American Medical Group Association. Typically, changes in rulemaking from the proposed to final rule are not what he would characterize as significant. But the final rule made it less risky and less burdensome for physicians to participate in ACOs and offered them more incentive to do so. See sidebar for a summary of changes from the proposed rule to the final rule; see this month’s Legally Speaking column, p. 13, for more on how antitrust regulations are being relaxed to allow ACOs to function and other background. >>
PARTICIPATION OPTIONS

With ACO formation starting this year, dermatologists should keep their ear to the ground to find out who is forming ACOs in their communities. Large integrated delivery systems (IDSs), independent physician associations (IPAs), multispecialty practices, and even hospitals are potential candidates for forming ACOs. A large IDS has the kind of comprehensive data regarding services and costs for coordinated care that is necessary to succeed as an ACO, noted Karen Edison, MD, who served on the AAD’s ACO Workgroup. An IPA offers physicians flexibility to practice independently and work together with other physicians to manage a population of patients in a coordinated way, noted Harold Miller, executive director of the Pittsburgh-based Center for Healthcare Quality and Payment Reform. Even now IPAs comprising primary care physicians (PCPs) and specialists are working together and managing global payment capitation quite successfully without hospital involvement, he noted.

An ACO must maintain good working relationships with specialists to avoid overlaps and gaps in care, as well as achieve the best outcomes for patients. “It would be hard for an ACO to achieve maximum potential unless it has primary care at the core,” Miller said. “Many argue it would be hard for an ACO to be successful without specialty physicians being engaged in some fashion.”

Dermatologists can participate in an ACO by becoming a member of a large multispecialty or specialty group, contracting with an existing ACO, gaining employment in a hospital that joins or forms an ACO, or joining a network of individual practices to form an ACO. An ACO with a high rate of dermatology referrals may want to hire a dermatologist to reduce or control its costs.

But dermatologists do not have to be a part of the ACO itself. For example, they can develop a contractual arrangement with an IPA or a large primary care practice-turned-ACO. Additionally, not all multispecialty groups employ all types of specialists, requiring them to develop relationships with some outside of the group.

CHOOSING THE ONE

Whichever entities form ACOs will be based on the realities of the marketplace, Roman said. That is why dermatologists should become familiar with the practice realities in their respective marketplace. What is the competitive landscape? Who are the payers? What are their referral patterns? “Choosing with whom to align will flow from these realities,” he said.

Referral networks are a key factor in deciding with whom to align formally or informally, Dr. Edison noted. Such physicians may include PCPs; other dermatologists; Mohs surgeons; plastic surgeons; oncologists; and ear, nose, and throat specialists. Pay attention to this on an organizational basis, as well, she recommended.

“Start to have conversations with other physicians in your community about the possibility of working together to better manage a population of patients,” Miller added.

Look for a group of physicians across specialties who want to improve quality, patient safety, and cost effectiveness because that’s where the value is driven that creates the opportunity to earn additional payment to physicians for their work, stressed Mark Shields, MD, MBA, senior medical director of Mt. Prospect, Ill.-based Advocate Physician Partners, which signed its first commercial ACO contract Jan. 1, 2011. “It’s all about finding that group committed to the right culture in a local setting.”

Additionally, dermatologists should learn about the different payment models, not just the SSP model offered by Medicare, Miller said. Under Medicare, dermatologists will be paid fee-for-service with the Shared Savings Program payment kicking in only if savings are realized. Other ACOs have different payment models that may be more appealing to dermatologists. “Keep in mind that Medicare patients may be a small subset of your patient population. Do you want to change your practice structure based on a payment change for a subset of patients or do you want to be able to have an organizational mechanism that will allow you to work with other physicians to care for this subset of patients?” he asked. “If you keep your foot in both camps, as the payment system evolves you can shift into a more coordinated structure.”

Dan McCoy, MD, former chair of the council on legislation for the Texas Medical Association, concurred. “At this point, there is no reason for dermatologists to jump ship from their current practice into a new employment model just to join an ACO,” he said. Consider the fact that the key to ACO success is creating value for the patient and the health system. Since the largest determinant of cost savings — and therefore value improvement as perceived by
many hospitals — is inpatient care, there may not be much incentive for these types of groups to favor dermatologists, he said. In contrast, single-specialty ACOs or multispecialty groups may shine a better light on the value that dermatologists can add in early diagnosis and more successful management of skin disease. “To date, there are very few ACOs that will offer a ‘return’ to the physician and fewer still that would reward a dermatologist,” he said, “so careful selection is paramount.”

Dermatologists should also be aware that some ACOs may opt to hire one dermatologist to manage a group of mid-level providers as this will potentially lower costs, Dr. McCoy warned. Dermatologists need to be prepared to show that they are an essential player in improving quality and outcomes and that the entire care of dermatologic patients cannot be delegated to mid-level providers.

Unlike PCPs, specialists have the option of joining more than one ACO. Whether dermatologists should

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**ATTRACTING ACOs**

Once you have decided to join and/or contract with an ACO, how can you set yourself apart from others?

“Dermatologists should think about opportunities to change the way care is being delivered that maintains or improves quality for patients and reduces costs for the payer,” said Harold Miller, executive director of the Pittsburgh-based Center for Healthcare Quality and Payment Reform. “There’s no standard formula for that. It has to be done specialty by specialty.” One way to determine those opportunities is to talk with PCPs to better identify subsets of patients who would most benefit from dermatologic care. Among those patient populations would be patients at risk for melanoma as well as those with eczema and psoriasis.

“Dermatologists should think about ways they can produce value, meaning enhancing the quality of patient experience, safety, or cost effectiveness, and how they can deliver those by themselves or in collaboration with other physicians,” added Mark Shields, MD, MBA, senior medical director of Mt. Prospect, Ill.-based Advocate Physician Partners. Be sure to share those ideas with PCPs and other specialists, he said.

In addition to evaluating dermatologic care with “the value proposition in mind,” working more closely with physician colleagues than in the past is a must, said Karen Edison, MD, who served on the AAD’s ACO Workgroup. Along those lines, see referred patients in a timely fashion and provide prompt clear communication back to the referring provider. In addition, be willing to see referred patients regardless of payment source and do hospital consults when asked — if not in person, then via teledermatology or reviewing high-quality digital photographs. Dermatologists may also want to think about how to help with preventive health care, such as asking patients if they have a PCP, checking blood pressure in the clinic, and even asking if patients have had their flu shot, she said.

Although most of the quality measures to be reported by ACO participants focus on primary care, dermatologists should become familiar with them to ensure that they understand the measures that relate, Dr. Edison said. Several measures addressing patient satisfaction, such as obtaining timely appointments, communicating effectively, providing access to specialists, and participating in shared decision-making are applicable to dermatologists. Medication reconciliation and qualifying for an EHR incentive payment are two measures that could apply to dermatologists.

“By doing these things,” Dr. Edison concluded, “you will be viewed as part of the care team.”
do so is up for debate. Given that creating better outcomes and value is a key to ACO success, joining more than one may hinder the dermatologist’s ability to deliver quality care, Dr. McCoy said. Although Dr. Shields believes that the decision is highly dependent on local circumstances, he noted that having a very close relationship with PCPs in one ACO is more important to delivering value than having mediocre relationships with PCPs in more than one. On the other hand, dermatologists will likely have patients belonging to multiple ACOs, especially in larger markets, and working with more than one will allow them to provide better care for all of those patients, Miller said. The potential future consequences of not participating include possibilities that dermatologists will have to consider as they think through their options. “You may be left out if payment mechanisms are truly redesigned to reward quality and value,” Dr. McCoy said. “And if you haven’t joined and put systems in place to document your quality of care, then you might find it difficult to be accepted into successful ACOs.” While ACOs are focused on primary care now, many policymakers predict that this type of payment reform will spread to specialty care, Dr. Edison added. Indeed, Ezekiel Emanuel, MD, PhD, a former health policy advisor in the Obama administration, recently suggested in a New York Times editorial that ACOs would supplant health insurers as the dominant coordinators of patient care by the end of the decade. “Who knows how long dermatologists will continue to be paid fee-for-service at this level?” Dr. Edison said. “At some point, dermatologists who don’t join an ACO may risk being left behind as provider payment reform rolls out.”

Who knows how long dermatologists will continue to be paid fee-for-service at this level?

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Personna DermaBlade is the sharpest on the market. Our exclusive MicroCoat® coating process allows blades to glide with smooth, clean precision.
Almost six years into a system overhaul, physicians share views on Massachusetts health reform and consider what it means for physicians nationally.
The upcoming presidential election has captured the nation’s attention, and at the very center of the maelstrom are the issues of health system reform and extending coverage to the uninsured. As Americans prepare for an election season full of heated rhetoric and important decisions, a pair of Massachusetts dermatologists and the director of their state’s dermatology society say that while the ultimate result of reform is still very much up for debate, there are a number of measurable effects from their state’s push toward reform — which laid the groundwork for the federal effort — that may offer a window into the next decade of medicine.

MASS MANDATE

2006 saw the culmination of Massachusetts Gov. Mitt Romney’s efforts to push forward comprehensive health system reform in his state. The law mandated that residents obtain a minimum level of health insurance coverage, and provided for completely subsidized insurance for residents at or below 150 percent of the federal poverty level and partially subsidized insurance for those earning up to 300 percent of the poverty level. In doing so, the state created an independent authority to connect residents with health plans for which they qualified, known as Massachusetts Health Connector. Individuals who didn’t comply with the mandate faced financial penalties. Businesses with at least 11 employees were required to make what the law termed a “fair and reasonable” contribution toward employee health coverage.

The individual mandate, according to Massachusetts dermatologist Louis Kuchnir, MD, has led to a fairly significant change in culture among health care patients in the state, which he said may partly explain the extremely low number of uninsured patients currently reported. The effect has been particularly clear to Dr. Kuchnir, who runs three practice locations and employs 24 employees, including six physicians and two nurse practitioners.
“One of the most apparent early effects of the reform was that people who had no insurance became self-conscious about it,” Dr. Kuchnir said. “They were a bit embarrassed because they were supposed to go online and get themselves covered through the Massachusetts Health Connector. They no longer viewed their lack of coverage as someone else’s fault.”

PATIENT AND STAFF EXPERIENCE
Concerns about universal coverage often focus on the possibility that doctors’ offices will be overwhelmed with patients, but Dr. Kuchnir said that to date, market forces have kept demand reasonably in check, considering the circumstances. A late-2009 survey by the New England Journal of Medicine bears out many of Dr. Kuchnir’s observations, with some physicians reporting longer waits, but an overall improvement in care for Massachusetts residents (see sidebar, page 29, for more information).

“Copayments have gotten so high that demand has been offset. They’ve increased substantially, as have deductibles,” Dr. Kuchnir said. “There is now a proliferation of very low-reimbursing plans that are available to folks who qualify by needs testing.”

As business owners, both Dr. Kuchnir and Pamela Weinfeld, MD, a Wellesley, Mass., dermatologist who runs her own small practice with a partner, have found that the individual mandate has affected them very little, if at all. Both physicians currently offer health benefits to their employees. Dr. Kuchnir said that since the requirements were much more modest than the benefits he already offered his employees, he’s made no changes in his practice’s employee health plan. Dr. Weinfeld, who has only offered employee health benefits for two-and-a-half years, said that while having employees sign up for coverage individually through the Health Connector was extremely easy, offering coverage to her office didn’t require much extra work. While the additional cost of providing insurance to employees is certainly a factor, she said, employers who elect not to provide health coverage to their employees must still provide what the state deems a “fair and reasonable” contribution toward coverage for their employees, with compliance monitored quarterly. Alternately, businesses can be asked to pay up to $295 per employee per year into the state’s Safety Net Trust Fund.

“In some ways, the mandate has made things easier for all practitioners. Before we offered insurance, it was a little easier for people to go and find it themselves on the Massachusetts Health Connector,” she said. “Since we’ve been offering insurance, it’s convenient in a different way. When we didn’t offer it, we had to make sure each employee had insurance individually. Now that we offer insurance, we have it covered, and for those who decline, we have to make them sign a document that they have insurance elsewhere.”

Following implementation of the legislation, the number of uninsured citizens in the state dropped dramatically, and currently resides in the low single digits, according to the state’s Division of Health Care Finance and Policy. This, according to Dr. Weinfeld, has been apparent in her day-to-day, and is one change that she says the majority of doctors find positive. It does, however, require practitioners to review their policies regarding various insurance providers.

“I think that in terms of being a provider, you don’t have a lot of situations where people don’t have insurance. But you do have situations where people have insurance that doesn’t pay very much and you have to decide whether you’re going to take it or not,” Dr. Weinfeld said. “Most of the teaching hospitals and academic centers accept all the different insurance, and it can be a difficult decision whether or not to accept every insurance or only some of the plans.” The lesson for doctors nationwide, about to encounter a similar growth in the number of patients with insurance of varying quality, may be to brush up on their contract-reading skills and rethink the right payer mix for their practices.

CONSOLIDATION AND PRIVATE PRACTICE
As might be expected with this first-of-its-kind overhaul, the landscape of medicine in the state has seen significant changes in a relatively short period of time. According to Massachusetts Academy of Dermatology executive director Paul Wetzel, three main insurers — Blue Cross Blue Shield (BCBS), Tufts, and Harvard Pilgrim — insure around 90 percent of patients. The small handful of major insurance providers, he said, is one of the initial factors that contributed to the state’s unique ability to lead the nation in health coverage reform.

The full implementation of a national plan, he said, would likely lead to similar state health insurance consolidation on a nationwide level. At the same time, Wetzel noted, hospitals like Beth Israel and Massachusetts General are expanding throughout the state, making inroads into communities traditionally served by private practitioners and community hospitals.

So far, he said, the results in Massachusetts have some physicians watching the situation with a careful eye. Hospital consolidations in the state, he said, have recently ramped up at an alarming rate, and a significant amount of both provider and insurer activity is concentrated between a handful of organizations.

“BCBS made a contract that would pay Partners doctors [physicians at the multi-hospital organization begun by Massachusetts General Hospital and Brigham and Women’s Hospital] well above and beyond what they would offer to the local community-based doctors. The state attorney general is now looking at that as a potential anti-trust violation,” Wetzel said. “At a time when everyone is worried about the rapidly growing cost of care, [and] one major insurer teams up with one of the major providers and agrees to pay them a lot more than they do the local physicians,” he said, it raises red flags.

“Dermatologists [around the country] don’t really operate in the hospital system sphere nearly as much — they’re very different than a lot of their specialist colleagues in that regard,” Wetzel said. “But the way medicine has traditionally worked is that a physician can open an office and practice medicine the way they see fit. One of the health plans in Massachusetts is now experimenting with reimbursing the patient if they research and find a cheaper option for treatment. It’s already begun with tests — lab tests and MRIs, for example. If a doctor says a patient has
to have blood drawn, the patient is in a position to say ‘how much will that cost?’ Then the patient can call around to different labs and find out that they can get it cheaper over at Laboratory X,” he said. “If they use that option and affect a certain reduction, the plan will send them reimbursement.” The result is doctors receiving results from a lab they have no relationship with, he said, a particular concern for dermatologists who value the relationship they have with the dermatopathologist they prefer to work with. “It all boils down to losing control of one aspect of the treatment of the patient,” he said.

Conversely, Dr. Weinfeld said, the growing power of hospital systems in the state has led to a number of immediate benefits for physicians.

“So far I’ve seen a number of positive benefits. I’m in a couple of different health care systems, and one has a really strong unified medical record, which is really incredible for coordinating care,” she said. “When the patient comes in, I can see every single note that their doctors in the system have entered, even though we’re not in the same practice structure. We’re able to access this system and coordinate care. The only concern is when an entity gets that powerful, what will it mean for the future? So I think that there’s a lot of uncertainty in Massachusetts, and people are a bit nervous about that concept.”

Under the nationwide health system reform law, it appears clear that consolidation of care organizations — already a concern for many community hospitals and small practitioners — may accelerate to a pace comparable to that of the Bay State. Like their Massachusetts brethren, though, doctors nationwide may see significant benefits in terms of both medical record integration and coordination of care.

LOOKING AHEAD
While significant progress has been made in expanding insurance coverage, Wetzel pointed out that the all-important second phase of the state’s health reform effort — controlling costs — is still in development. Gov. Romney’s roadmap, he said, always included getting the majority of the state insured during the first push, then focusing on cost controls and efficient delivery of care. (In contrast, the national health reform law included both insurance expansion and cost-control experiments.) The development of cost controls in Massachusetts, he said, is something dermatologists and other specialists will watch extremely closely.

“That program only works currently because about half the cost of it has been subsidized by the federal government since it was enacted,” Wetzel said. “The most common expression that you’ll hear about it — especially with the campaign going
on and Gov. Romney talking about it and everyone else talking about him — is that it wouldn’t work nationally, or couldn’t, unless the federal government would subsidize half the cost in every state. While it appears to be working, the cost of it has been a bit masked.”

In the last year, though, discussion about cost control has started in the legislature. “Most of the conversation involves the primary care part of the deal. The specialists, including derms, often aren’t even mentioned or discussed,” he said. “The current governor [Deval Patrick] has said that the foundation of any kind of cost control would be a global fee. That’s probably the most significant part. When they talk about a global fee for someone who goes to a primary care doc with a chest cold and then gets farmed out to pulmonary treatment for emphysema, that’s one thing, but derms are another. More than half of their business isn’t through referrals. The question is whether they have to join a group. We’ve had discussions about whether our [Massachusetts Academy of Dermatology] could potentially form an ACO.”

However Massachusetts resolves its cost-control problems, Dr. Weinfeld said, is sure to have a sizable impact on the national discussion. Much of what’s been on the table, she said, is already present with slightly different vocabulary in other states.

“This isn’t all reform per se, but the way health care is structured in Massachusetts with hospital systems and insurers playing a big role will illustrate how national reform is handled,” Dr. Weinfeld said. “The rest of the country will see this soon in the form of ACOs.” (See article, p. 20, for discussion of how ACO development may affect dermatologists.)

The X factor in this entire discussion, Dr. Kuchnir said, is politics. While the national health reform law and the Massachusetts plan share a number of logistical similarities — except an increased focus on cost control from the inception of the national plan — party divides and process throw them into stark contrast.

“The Massachusetts plan was the initiative of a Republican governor who was working with strongly Democratic majorities in both houses of the legislature. It was bipartisan from its inception through the hearings and discussions in its adoption,” Dr. Kuchnir said. “By contrast, the national plan was passed without a single Republican vote and no Republican support. It was a vision for universal coverage conceived and passed without any bipartisan compromises. As a result, the national experience is likely to develop in a different way than the Massachusetts experience.” dw

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TARGETED THERAPIES TAKE AIM AT SKIN CANCER

New technologies drive advances in treatment

BY RUTH CAROL, CONTRIBUTING WRITER
Dermatologists who specialize in treating skin cancer are heralding events of the past year as real breakthroughs in battling deadly and disfiguring forms of the disease. In 2011 the U.S. Food and Drug Administration (FDA) approved two new drugs for the treatment of advanced metastatic melanoma, as well as a device that helps dermatologists select which lesions to biopsy for melanoma. In addition, the FDA approved a promising new treatment of advanced basal cell carcinoma (BCC), vismodegib, on Jan. 30 (see p. 8). In the meantime, for the growing population of frail elderly patients with BCC and squamous cell carcinoma (SCC), technological advances are prompting a new look at superficial radiation therapy, a once-common modality that experienced a gradual decline after the 1970s (see sidebar, p. 36).

ONE GOAL, TWO APPROACHES

With melanoma incidence and mortality both on the rise, the emergence of two drugs that effectively combat the disease at its most advanced stage sparked excitement and enthusiasm. “With these new treatments, even some patients with brain metastases, where most treatments are completely ineffective, are responding, which is quite miraculous,” said Allan C. Halpern, MD, chief of the dermatology service at Memorial Sloan-Kettering Cancer Center. “They have completely different mechanisms of action, which in some ways makes it even more exciting, because it means we’ve opened up two fronts against the disease.”

Ipilimumab, approved last March, is a monoclonal antibody that blocks the molecule cytotoxic T-lymphocyte antigen (CTLA-4), which is thought to act as a brake on the immune system. “Ipilimumab basically counteracts the inhibition of the immune attack against the melanoma cells and allows that attack to proceed more effectively,” said Martin A. Weinstock, MD, PhD, chief of dermatology at Providence VA Medical Center and professor of dermatology and community health at Brown University’s Warren Alpert Medical School. >>
In a phase three study of 676 patients with unresectable stage III or stage IV melanoma, published in the New England Journal of Medicine (2010;363(8):711-23), the patients received ipilimumab plus a glycoprotein 100 (gp100) peptide vaccine, ipilimumab alone, or gp100 alone. Median overall survival was 10 months among patients receiving ipilimumab plus gp100, 10.1 months for those receiving ipilimumab alone, and 6.4 months among those receiving gp100 alone. The ipilimumab-alone group had a two-year survival rate of 24 percent; this makes ipilimumab the first treatment ever to improve overall survival in advanced melanoma patients, Dr. Halpern noted. The most common adverse events were immune-related and most often affected the skin and gastrointestinal tract. Another phase three study, also published in NEJM (2011;364(26):2517-26), found a three-year survival rate of 20.8 percent in patients treated with ipilimumab plus dacarbazine versus 12.2 percent in a group treated with dacarbazine plus placebo. “The hope is that some of these patients who have responded completely to ipilimumab will be cured of their disease,” Dr. Halpern said. Dr. Rigel remarked that MelaFind could “be particularly useful in patients who present with late-stage melanoma was the FDA’s approval of groundbreaking technology designed to help dermatologists detect melanoma in its earliest stage. MelaFind, a hand-held imaging device approved in November, projects light of 10 different wavelengths (from blue to near infrared) on a lesion. The resulting image is analyzed using an algorithm developed from a database of 10,000 biopsied lesions. A “positive” finding is considered evidence to support biopsy, not a diagnosis of melanoma. It is intended for use only by dermatologists who have completed a training program, and only on pigmented lesions meeting specific criteria. “Right now we’re kind of in the dark ages in terms of finding melanoma early,” said Dr. Rigel, who is on the scientific advisory committee for Mela Sciences, the makers of MelaFind. “It’s very subjective; we can’t quantify why a spot is melanoma but can only say ‘it looks like one.’ MelaFind is very easy to use, the results are available within a couple of seconds, and it’s not expensive. It’s been tested on a large data set and demonstrated a 98.4 percent sensitivity in identifying melanoma. I use dermoscopy, and this, to me, is like dermoscopy on steroids.” Dr. Halpern and Dr. Weinstock cautioned that the utility of MelaFind and its role in the dermatologist’s practice remain to be seen. “How they roll this out over the next year, what we’re using it and is it proving helpful, are going to be absolutely critical to its diffusion into practice,” Dr. Halpern said. Dr. Rigel remarked that MelaFind could be particularly useful in patients who present with
NEW DRUG BATTLES BCC ON TWO FRONTS

Vismodegib offers the first effective treatment for patients with inoperable, advanced BCC and a welcome alternative to multiple surgeries for those with basal cell nevus syndrome (BCNS). The drug binds to and inhibits Smoothened, an activator of the hedgehog pathway that is implicated in 90 percent of BCC tumors (see sidebar). Results from the pivotal phase two trial submitted to the FDA by Roche showed that vismodegib substantially shrank tumors or healed visible lesions in 43 percent of patients with locally advanced BCC and 30 percent of patients with metastatic BCC. (The study included 96 patients.) Based on those findings, the FDA granted the drug priority review status in October 2011 and approved the drug Jan. 30.

A second vismodegib trial, an investigator-initiated phase two study, boosted optimism even further when it was found that the drug can prevent new BCC tumors as well as shrink existing lesions. “We tested the drug on patients with basal cell nevus syndrome, also known as Gorlin syndrome,” said Jean Yuh Tang, MD, PhD, assistant professor of dermatology at Stanford University School of Medicine. “Some of these patients have really severe disease, with as many as 200 tumors. The only treatment options are Mohs surgery, standard excision, or electrodesiccation and curettage. These are all destructive and scarring, and a lot of our patients have significant morbidity because they’ve had so many surgeries.” Dr. Tang and principal investigator Ervin Epstein, MD, enrolled 47 adults with BCNS and randomized the subjects to receive either vismodegib or placebo. “The data safety monitoring board met and voted to end the placebo trial because vismodegib had an overwhelmingly positive effect,” Dr. Tang said. “In patients treated with the drug, we saw about two new BCCs per year, while patients in the placebo group developed 29 new BCCs.” The aggregate size of existing BCCs in the treatment group decreased by 24 cm, compared to 3 cm in the placebo group. Interim results of the study were presented at the 2011 annual meeting of the American Academy of Dermatology in San Francisco.

THWARTING THE HEDGEHOG

Researchers pursuing ways to disrupt the hedgehog pathway are taking aim at the culprit involved not only in the most common form of skin cancer but in other cancers as well. “I believe six or seven companies are now developing hedgehog pathway antagonists, including some topical agents. It’s very exciting for dermatologists because hedgehog was first discovered as a cancer pathway in basal cell carcinoma, but it is now implicated in many internal cancers, including pancreatic, ovarian, colorectal, brain, muscle, and stomach cancer,” said Andrzej Dlugosz, MD, Poth Professor of Cutaneous Oncology in the departments of dermatology and cell and developmental biology at the University of Michigan. “What we’re learning about the hedgehog pathway in BCC might be applicable to some of those lethal cancers.”

Dubbed “one of the orchestrators of embryonic development” by Dr. Dlugosz, the hedgehog pathway drives the development of many different organs during embryogenesis but is not required or active in most adult tissues. “If you can block it in patients with hedgehog pathway-driven tumors, it’s theoretically not going to do much to the rest of the body but it should work on halting the cancer,” Dr. Dlugosz explained. “That provides a level of selectivity that many other drugs do not.” One interesting exception where the hedgehog pathway is important in normal tissue is the growing hair follicle, which explains why some patients taking these drugs note hair loss.

The results of an ongoing study of vismodegib in patients with basal cell nevus syndrome (see main story) were “very exciting,” Dr. Dlugosz remarked. But he noted that two major issues remain unresolved: whether residual tumor cells remain, and whether a patient’s tumor cells will develop resistance to a hedgehog-targeting drug. “With BCC, we know that in advanced tumors that have seen other, DNA-damaging treatments, resistance can develop,” he said. “But there’s no evidence that previously untreated BCCs acquire resistance, at least based on the work that Drs. Jean Tang and Erv Epstein have been doing. This could be very exciting for dermatology patients, but it will be important to understand why tumors reappear when the drug is stopped.”
A NEW LOOK AT RADIATION THERAPY

For Mohs surgeon Armand B. Cognetta Jr., MD, superficial radiation therapy (SRT) offers an essential alternative to surgery for elderly patients with basal cell and squamous cell carcinoma, a segment that is growing rapidly. “The number of Americans 85 and older is projected to increase from 5.8 million in 2010 to 8.7 million in 2030,” said Dr. Cognetta, who is founder of Dermatology Associates of Tallahassee and associate professor of dermatology at Florida State University School of Medicine. “These patients tend to be frail, sicker, on multiple medications, and use pacemakers and other medical devices. If we can avoid surgery on them, we should.” In addition, SRT may be appropriate for particular disease sites, Dr. Cognetta said. “In certain anatomical areas, such as the rim of the nose or the eyelid, that require very complex and disfiguring closures, radiation leaves a minimal scar. Radiation can also be very effective on large areas of the scalp that would require a graft or flap if surgery were performed.”

Allan C. Halpern, MD, chief of the dermatology service at Memorial Sloan-Kettering Cancer Center, agreed that SRT can be a good option for non-melanoma skin cancer in frail, elderly patients. “While it is the exceptional case in which we use it, it can be a very effective and well tolerated therapy,” he said. “One of the biggest challenges in the medical community at large is the paucity of practitioners with adequate experience treating skin cancer with this modality.”

Broadly used in the 1970s, SRT gradually fell victim to obsolescent technology, the advent of Mohs surgery, and a decline in residency training, Dr. Cognetta said. “When I started using radiation therapy 28 years ago, probably 75 percent of dermatologists had radiation machines in their office or had access to them, and today there are probably 200 to 300 dermatologists in the country still using it,” he noted. Early equipment contained rheostats and vacuum tubes that became difficult to repair and impossible to replace, and U.S. manufacturing of superficial radiation machines ceased in 1970, Dr. Cognetta explained. “Older practitioners passed down their units, and many ended up being junked. About 10 years ago, a company in England built the first solid-state photon radiation machine. Now two manufacturers sell equipment for superficial radiation therapy in the U.S.” (Dr. Cognetta is an advisor to and investor in Sensus Healthcare.)

The sophistication and ease of use of modern photon radiation equipment, coupled with a high cure rate, are leading to a quiet resurgence in SRT, Dr. Cognetta said. “All modern units have variable kilovoltage and internal filtration that allow us to plan treatment and carefully calibrate dose delivery, and they automatically stop once the cumulative amount of radiation you have selected is delivered,” he explained. “We just completed a study of more than 1,500 cases over a 10-year period, and our overall cure rate was in the 95 percent range for BCCs, SCCs, and SCCs in situ.” The study will be presented at this month’s AAD Annual Meeting and has been submitted to the Journal of the American Academy of Dermatology for publication.

Although he does not track sales of the units for either manufacturer, Dr. Cognetta believes SRT is attracting a new generation of dermatologists who are adept at using a variety of laser platforms, many more complicated than photon SRT. “Dermatologists were always in the forefront of this modality, and it’s very gratifying to see that there’s a resurgence,” he said. “While the cure rate is not as good as Mohs, it is a very gentle, less costly, and in some cases a superior modality for our older and frail patients.” And, it’s a modality best left to dermatologists, he noted. “Dermatologists are in a better position to not only understand the various skin cancer subtypes and judge tumor depth and tumor borders, but also to be able to select the best method of treatment based on each individual patient’s specific tumor and health status.”
Thank you for the honor of being your president for the next year. I’m excited by this opportunity to serve the specialty of dermatology at a time when we face so many important challenges, and when so many exciting opportunities are within our grasp.

You may want to know what perspective I bring to this job. I was born in Brooklyn, raised in Queens, and went to Stuyvesant High School. I’ve been practicing dermatology in Suffolk County since 1990. But in between, I headed to upstate New York, where I was in the six-year medical program at Rensselaer Polytechnic Institute and Albany Medical College with our outgoing president, Ronald Moy, MD. I then completed a residency in Dallas and a fellowship in Houston, followed by a year and a half on faculty in Dallas, after which I went to Vermont for two years before returning to New York.

Since coming home, I’ve still made my way around the country for dermatology. I started out serving on committees and task forces of the Academy early in my career, with some focus on payment policy issues. That led to Brett Coldiron, MD, calling me late in the 1990s and asking if I would serve on a new group being formed, the Practice Expense Advisory Committee, to provide information to the AMA Relative Value Update Committee, or RUC, regarding the money spent on what are called direct practice expense inputs — the gauze and tape and other supplies associated with each of thousands of CPT codes. I served on the PEAC for four years, after which I became the Academy’s representative on the RUC. I am proud of the work I did to help ensure that dermatologists and other physicians are paid accurately for what we do.

In addition to these experiences, you may know me as a frequent speaker on electronic health records and other technology-related topics. Long before anyone dreamed of government incentives to adopt EHRs, I was intrigued by the possibilities such computer technology might offer as well as the pitfalls I knew, or learned, would have to be avoided to make EHR use worthwhile for dermatologists and of benefit to our patients. Back in the early days, sessions on EHR were often hypothetical, or based on limited experiences, but today our specialty has seen significant EHR adoption. As your president during the year when the government offers the last possible opportunity to earn the maximum meaningful use bonus for adopting an EHR — $44,000 over five years for Medicare participants — I will be active in ensuring that we continue to provide the guidance you need to make the right choice. From in-person sessions at the Annual Meeting in San Diego, including a demonstration of different systems, to the Academy’s online HIT-Kit, available at www.aad.org/hitkit, the Academy can help you figure if the time for you to adopt is now.

Of course, the continuing impact of health system reform on dermatologists and our patients is another critical issue I will monitor as your president. We will all watch with interest as the Supreme Court weighs the law this spring, and as the American people consider it as part of this fall’s election. Whatever the outcome of the case and the vote, the Academy will work to ensure that you have the resources you need to deal with the coming change.

Indeed, the Academy offers a wealth of resources to help you meet the challenges of practice, from webinars on coding issues (see www.aad.org/webinars to register) to programs that help you to fulfill the components of the American Board of Dermatology’s Maintenance of Certification program (see www.aad.org/education-and-quality-care/moc for more information).

The coming year will be an exciting one. Dr. Moy and I will be available in the AAD’s booth in the exhibit hall in San Diego on Monday, March 19 from 1:30 to 2:30 p.m., and I welcome you to stop by and share your thoughts with us. dw
Partnership between physicians and staff key to Academy’s success

EXECUTIVE DIRECTOR’S REPORT

AS MEMBERS OF THE AMERICAN ACADEMY OF DERMATOLOGY, I have no doubt that those of you reading this column recognize and appreciate the level of effort expended on your behalf by your colleagues. Whether it be the president, Ronald Moy, MD, and vice president, Suzanne Connolly, MD, who have served you for the last year or their successors, Daniel Siegel, MD, and Zoe Diana Draelos, MD, who will take office this month, or the numerous members who volunteer on our committees and task forces, you know the sacrifices they make and the hours they put in to ensure that this organization best serves you and the specialty.

What you may not know, and what they would no doubt tell you, is how critical the partnership between our physician leadership and volunteers and our professional staff is to the Academy’s success. Part of the value the Academy offers to its members is a staff dedicated to dermatology, with particular expertise that allows them to work with members to develop strategies and tactics for dealing with issues and then to carry out those strategies together.

For example, last year the leadership realized that developing appropriate use criteria (AUC) for Mohs surgery would allow us to ensure that our voice was heard as decisions about when the technique should be reimbursed were made, and thus would be important to the specialty’s future. The work of drafting and evaluating the criteria involved hours and hours of contributions from nearly 80 physicians across various parts of the specialty. Their efforts were indispensable.

All of their time and effort was supported by the expertise and effort brought to bear on the development of AUC by staff across our organization. Science and research staff gathered the available medical literature and graded it. Staff in practice management and coding offered data and observations regarding how Mohs is currently used and how changes could impact dermatology practices. Staff in the legislative, regulatory, and payer advocacy areas ensured that the process answered the right questions to make the resulting document a meaningful one for use in advocating for fair reimbursement. Our communications staff will be vital in ensuring that our efforts in this area are properly accounted by the media if and when such questions are asked.

The development of the AUC, which will be published this spring, is one example among many of the way that physicians and staff work together to make everything the Academy does — our public education, our advocacy efforts, our Annual Meeting — the best it can be. When you see your colleagues who serve the Academy this month in San Diego, by all means, thank them for all of their efforts on your behalf. But if you happen to bump into a member of the Academy’s staff, feel free to thank them, too. The Academy would not be as successful as it is without them.
2012 Academy election opens March 17
THE CANDIDATES FOR THE 2012 ACADEMY ELECTION were announced on Feb. 28, 2012 via email.

The Academy’s election link, www.aad.org/election, will be accessible starting Tuesday, March 6. This site contains all the candidates’ background materials, the ballot book and the proposed amendment to the bylaws. The president-elect speeches delivered at the Annual Business Meeting and videotaped candidate statements will be posted to the election site by Tuesday, March 20.

The 2012 AAD Election officially opens on March 17 at 12:01 a.m. ET. Eligible voting members of the Academy are urged to cast their votes. Members can conveniently access the Academy election site at www.aad.org/election or use the direct link at https://www.esc-vote.com/aad2012 to vote online.

When voting, you will be asked to provide a secure access code and your AAD member identification number. Access codes were sent to all eligible voting members on Feb. 17 via email or mail (for those without email addresses on file).

U.S. POSTAL SERVICE ANNOUNCES DELAYS IN SERVICE
The U.S. Postal Service recently announced the closing of 250 mail processing centers across the country and cuts to first-class mail delivery service. These changes may delay the delivery of the 2012 AAD Election Ballot Packet as well as election ballots submitted by mail. To ensure your vote is received, please view the online AAD Election Ballot Packet and cast your vote at www.aad.org/election.

If you require assistance with your secure access code during the Annual Meeting on Saturday, March 17 or Sunday, March 18, please contact Election Services Corporation (ESC) between 10 a.m. and 6 p.m. ET at its toll free number, (866) 720-4357 or via email at aadhelp@electionservicescorp.com. After the Annual Meeting, ESC will be available Monday through Friday from 9 a.m. to 5 p.m. ET.

VOTING DEADLINE IS APRIL 16
Paper and online voting concludes for all members on Monday, April 16. Ballots must be received or electronically posted on April 16 by 11:59 p.m. ET. – JOAN TENUT

Murray Gruber, founder of Dermik, mourned
MURRAY GRUBER, WHO FOUNDED DERMIK LABORATORIES and endowed two of the lectures given during the plenary session of the American Academy of Dermatology’s Annual Meeting, died Jan. 10. He was 94.

A pharmaceutical chemist by training, Gruber’s association with dermatology began in 1951, when he developed the first crude coal tar shampoo on the market. In 1972, he established the Lila Gruber Cancer Research Award and Lectureship to honor the memory of his first wife. He also endowed the Marion B. Sulzberger, MD, Award Lectureship in 1983, honoring basic research that has led to better understanding of clinical medicine.

The Academy honored Gruber in 1980 by awarding him the Presidential Citation in recognition of his contribution to dermatology. He was also made an honorary member of the Academy, and held honorary memberships in the Noah Worcester and American Contact Dermatitis Societies. In 1993, he established the latter’s Alexander Fisher Resident Award Program.

Eugene J. Van Scott, MD, an early recipient of the Lila Gruber Memorial Cancer Research Award and Lectureship, is one of many dermatologists who was aware of Gruber’s impact on the profession. “He was an innovative and entrepreneurial pharmacist who ventured to provide dermatologists with special compounded formulations,” Dr. Van Scott said.

Gruber is survived by his wife, Helen, and three children, Barry Gruber, Daryl Kulok, and Sharon Draghi. – RICHARD NELSON
Obituaries

The Academy recently learned with sorrow of the passing of the following members of the dermatologic community.


Thomas Jackson Cook, MD, 77, Norwich, Conn. Completed dermatology residency training at University of Chicago. Died Nov. 24, 2011.


Murray Gruber, 94, Rosslyn, N.Y. Died Jan. 10.

Paul E. Hilton, MD, 84, Joplin, Mo. Completed dermatology residency training at University of Missouri Medical Center. Died April 1, 2011.

Raymond Henry King, MD, 87, Double Bay, New South Wales, Australia. Completed dermatology residency training at Royal Prince Alfred Hospital, New South Wales, Australia. Died June 3, 2011.


Eugene Schoenfeld, MD, 72, Barrington, R.I. Completed dermatology residency training at SUNY at Buffalo. Died April 9, 2011.


Obituaries are published in Dermatology World after information is submitted to the AAD. Information on member obituaries should be submitted in writing to Member Resource Center, AAD Member Services Dept., P.O. Box 4014, Schaumburg, IL, 60168-4014, via fax at (847) 330-1090, or via email at mrc@aad.org.

Follow news about Annual Meeting on Twitter

ATTENDEES WHO USE TWITTER can follow @AADMtgs to get the latest news and updates about the 70th Annual Meeting in San Diego this month. The feed will note room changes and other program updates, offer special deals on AAD products, and give members the opportunity to engage in discussions about great sessions with each other. To follow the meeting Twitter feed, visit www.twitter.com/aadmtns.

You can join the conversation! Add the hashtag #AAD12 to your meeting-related tweets.

Grants for residency electives available

THE ACADEMY SEEKS APPLICATIONS FOR GRANTS that give dermatology residents the opportunity to complete electives in Botswana or with the Indian Health Service in Chinle, Ariz.

RESIDENT INTERNATIONAL GRANT

The Education and Volunteers Abroad Committee will provide funding for 12 U.S. or Canadian senior dermatology residents to participate in a four- to six-week elective in 2013 in Gaborone, Botswana. Participants will rotate between the Princess Marina Hospital and the Baylor International Pediatric AIDS Initiative. The grant allows dermatology residents an opportunity to learn about the care of tropical and HIV-related dermatologic conditions, as well as how to practice routine dermatology with finite resources. Residents are expected to prepare lectures and presentations, develop a database of photos, submit teledermatology consults, and present a report of activities to the Academy and their home programs. Rotations will take place in 2013.

Applications for rotations to be completed between January and June 2013 are due April 27, 2012; applications are due Sept. 28 for rotations to be completed between July and December 2013.

NATIVE AMERICAN HEALTH SERVICE RESIDENT ROTATION

Funding is also available for four U.S. dermatology residents currently in their second or third year of residency to participate in a one- to two-week rural health elective in Chinle, Ariz., at the Indian Health Service. Residents will have an opportunity to provide dermatologic care to the Navajo Nation population. Rotations will take place in March, May, August, and November 2013. Applications are due April 30, 2012.

Previous scholarship recipients are not eligible for either elective. Visit www.aad.org/education-and-quality-care/awards-grants-and-scholarships for more details or to apply. – COURSE BADIANE DW
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Thomas Waldinger, MD, wins Arnold P. Gold Foundation Humanism in Medicine Award

In recognition of his career-long dedication to compassionate patient care, Dearborn, Mich., dermatologist Thomas Waldinger, MD, has been chosen as the recipient of the Arnold P. Gold Foundation Humanism in Medicine Award, presented with the American Academy of Dermatology. Dr. Waldinger was nominated for his continuous efforts to share the perspective of patient-centered care with other physicians.

Dr. Waldinger greatly identifies and empathizes with cancer patients and their families. He collected his thoughts and experiences into a book, The Wisdom of Life Through My Patients, in 2000, which featured experiences and philosophy from more than 100 of his patients. The book proved popular, and Dr. Waldinger penned a follow-up book in 2009.

“I am greatly honored to receive this award,” Dr. Waldinger said. “The basis for treatment of a patient is medical science but the fundamental core value of medicine is humanism. I have always believed that a physician should take a personal interest in each patient because this will enrich both the patient and the physician,” he said. “In the process of using our medical knowledge to help our patients, we can be inspired by their courage as they face formidable health challenges and also be enriched by their wisdom. The essence of humanism is compassion and kindness which in the practice of medicine sustains both the patient and the physician.”

The award was created by the Arnold P. Gold Foundation to recognize physicians who demonstrate exceptional commitment to patient care. Since 2010, the Academy has co-presented the award with the Gold Foundation. To learn more or nominate someone, visit www.aad.org/education-and-quality-care/awards-grants-and-scholarships/gold-foundation-humanism-in-medicine-award.

Members Making A Difference: Steven Flax, MD

DERMATOLOGIST PROVIDES CARE IN SOUTH AMERICA

WINCHESTER, VA., DERMATOLOGIST STEPHEN FLAX, MD, found himself looking for volunteer opportunities abroad a few years ago. When he wasn’t able to find many, he helped pave the way for himself and other dermatologists to participate in more volunteer endeavors in countries throughout the world.

After becoming involved with Health Volunteers Overseas (HVO) and taking a trip to the organization’s site in Peru, Dr. Flax helped HVO set up a volunteer site in Costa Rica. He now vets candidates who approach HVO about offering their services at the volunteer site.

“I enjoy helping people who don’t receive the standard of health care that we enjoy in this country.”

• The first trip Dr. Flax took overseas — to Ecuador — opened his eyes to the necessity of improving medical care globally. “We did the clinic on what was basically a garbage dump,” he said. “There was one child I saw who needed surgery. I couldn’t do it on site, so we had to find a private dermatologist who would let me use his office for the procedure.”

• Despite not being in an academic setting, Dr. Flax has participated in educational trips, doing the extra work to lecture three to four days a week to medical students in South America — work he said he enjoyed greatly. “They’re very book smart in those areas. What they lack is the resources. They’re most interested in how we do it here,” he said. “They’re interested in viral diseases, especially warts, which are difficult to treat no matter where you are.”

• In addition to his work overseas, Dr. Flax sees patients from three local free clinics in his office on a referral basis. He provides treatment, procedures, and pathology services to patients free of charge.

• “I like doing service work. If anything, I wish there were more opportunities through secular organizations to do dermatology-specific service work abroad,” he said. “I like seeing the way they do things in other countries and exchanging ideas with dermatologists there.”

To nominate a physician, visit www.aad.org/membersmakingadifference.

Media Highlight

In 2011, the Academy provided journalists with more than a thousand referrals to AAD SKIN Faculty member dermatologists. These Academy referrals provide dermatologists with the opportunity to share the latest news and research in dermatology to positively position the specialty.

In the “Got Dry Skin?” article in the February issue of Ladies Home Journal (circ. 3,267,239), Arielle Kauvar, MD, Mary P. Lupo, MD, and Cheryl Karcher, MD, provided solutions to fix winter skin problems. To read this article and other dermatology news, visit the Academy’s online Media Relations Toolkit at www.aad.org/member-tools-and-benefits/media-relations-toolkit.

- ROSE PASOWICZ
PRACTICES FOR SALE

TEXAS
Visit us at the AAD Career Fair booth 24.

NEW YORK, NEW YORK
32 year-old well respected solo Park Avenue dermatology practice with large referral base for sale. Mix of medical and cosmetic dermatology. Could easily be expanded to offer more cosmetic and surgical procedures. Email: mtderm@aol.com.
Visit us at the AAD Career Fair booth 59.

SOUTHERN ARIZONA
Starting salary $750,000
Visit us at the AAD Career Fair booth 5.

PROFESSIONAL OPPORTUNITIES

TUCSON, ARIZONA
Leading dermatology practice specializing in adult, pediatric, & cosmetic dermatology and laser & skin surgery (e.g. Mohs) seeks experienced BC/BE general dermatologist to grow with our exceptional team of five providers and 20 support staff. A highly competitive salary & benefit package with partnership potential awaits the ideal candidate. Please submit a CV and letter of interest to Rachel Chánes at rchanes@pimaderm.com. Please visit pimaderm.com for more info.
Visit us at the AAD Career Fair booth 40.

BOULDER, COLORADO
Established Mohs/Cosmetic dermatology practice seeks exceptional BC/BE dermatologist to take over all general dermatology. State-of-the-art office, excellent staff, established EHR, outdoor activities abound. Guaranteed salary and incentives. Please submit a CV and letter of interest to cdevore.dsb@gmail.com or fax to (303) 442-2696.

St. Petersburg, Florida - Immediate Position Available on Florida’s Beautiful Gulf Coast:
Immediate position available for a full or part time BE/BC general/cosmetic dermatologist to assume an existing busy dermatology practice within a large multispecialty group. This opportunity includes working alongside a full time Mohs Surgeon and comes with an unlimited potential for growth. An interest in dermatopathology is a plus. Expected annual income is based on productivity and is competitive. Office is moving to a brand new state-of-the-art facility in 2013.
Interested candidates should contact Kelli Drayton at: kelli.drayton@baycare.org or (727) 502-4176.

SALES INFORMATION

UPCOMING DEADLINES FOR FUTURE ISSUES:
May ......................... March 26
June .......................... April 25
July .......................... May 25
August ...................... June 25
September ................... July 25
October ...................... August 24
November .................. September 25
December .................. October 25

Bonus Distribution Issues
August; Summer Academy Meeting
October; ASDS Annual Meeting

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Immediate position available for a full or part time BE/BC general/cosmetic dermatologist to assume an existing busy dermatology practice within a large multispecialty group. This opportunity includes working alongside a full time Mohs Surgeon and comes with an unlimited potential for growth. An interest in dermatopathology is a plus. Expected annual income is based on productivity and is competitive. Office is moving to a brand new state-of-the-art facility in 2013.
Interested candidates should contact Kelli Drayton at: kelli.drayton@baycare.org or (727) 502-4176.
PROFESSIONAL OPPORTUNITIES

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Come live and work in beautiful Southeast Idaho in a congenial, well-established practice. Idaho Falls is a safe, family-oriented city with a metro population of about 130,000 nestled against the foothills of the Rocky Mountains—just a short drive to Yellowstone National Park and the Teton Range. The surrounding mountains and forests boast world-class backpacking, fly-fishing, skiing and snowmobiling. Ours is a well-respected practice of two physicians and one physician assistant. We are seeking a BC/BE dermatologist to join us. The practice has concentrated on cutaneous oncology and surgery but continues to see many general dermatology patients daily. Salary and benefits are generous, and there is a possible quick track to partnership. Be a part of a dynamic group where your talents, ideas, and work are valued and where we celebrate the fact that there is also a beautiful life beyond the clinic doors. Please contact info@highvalleydermatology.com or visit us at the AAD Career Fair booth 20.

OMAHA, NEBRASKA

Dermatology Academic Opportunity! This opportunity is for a BC/BE assistant or associate professor, and we will consider candidates completing training in 2012. We are a busy academic medical center with a Level I trauma designation with one dermatologist, a dermatopathologist and two skilled nurse practitioners. In this position you will have an opportunity to excel in teaching and research while developing a rewarding general and surgical practice. Cosmetics optional and supported if interested. Competitive salary plus productivity bonus and generous benefits. To apply or learn more, please send your CV to: Lori Pinkerton, lpink@creighton.edu or call (402) 280-5747.

NEW HAMPSHIRE

Mohs Surgeon Needed

Fellowship trained Mohs surgeon sought for 2 days per month. Established practice. Contact Jeff Queen, (866) 488-4100 or hr@mydermgroup.com. www.mydermgroup.com. Visit us at the AAD Career Fair booth 5.

PRINCETON, NEW JERSEY

- Well-established practice looking to expand
- Vibrant university town close to Philadelphia & Manhattan
- State-of-the-art facility opened in July 2010
- Competitive salary & benefits

Contact Jayme at (609) 924-7690 www.princetondermatology.com

RECRUIT YOUR NEXT OPEN POSITION THROUGH DERMATOLOGY WORLD’S PRINT AND DIGITAL VERSION. FOR MORE INFORMATION CONTACT CARRIE PARRATT AT (847) 240-1770 OR CPARRATT@AAD.ORG

NORTHERN NEW JERSEY

A leading aesthetic medical practice is looking for a full time, BE/BC dermatologist to primarily work in two beautiful offices in New Jersey but flexible to work in Manhattan as needed. Consideration will be given to strong candidates that have just successfully completed residency. NJ License Preferred. Candidate must be enterprising with a real interest in the entrepreneurial – a practice builder. Excellent compensation and benefits including productivity incentive and generous vacation. For more information contact Laura Dougherty at (732) 356-1666 or ldougherty@reflectioncenter.com.

SOUTHERN NEW JERSEY

Great opportunity for BC/BE dermatologist in Medford, NJ. Beautiful community near Philadelphia, PA and Cherry Hill, NJ. Well-established busy dermatology practice in a brand new facility, with associated medical spa. Opportunity for competitive salary, benefits, and practice ownership. FT/PT position available. Email inquiry or CV to Becky@accentderma.com.

NEW YORK

Fellowship position available. Laser & Skin Surgery Center of New York, under the direction of Roy G. Geronemus, M.D., has an immediate opportunity for a full time clinical position in our active laser and related technologies research program. The physician will have an opportunity to participate in clinical trials involving new and evolving treatments for a wide variety of medical and cosmetic conditions. Publication and lecturing opportunities should be numerous. Dermatology training is a preferred prerequisite, but not essential. Salary will be commensurate with experience. Interested candidates should contact mail@laserskinsurgery.com for consideration.

NEW YORK

We are seeking a personable, patient focused, energetic, and well trained BC/BE dermatologist with an interest in performing a full spectrum of dermatologic and cosmetic procedures to join our practice immediately. We are offering an outstanding percentage-based contract with flexible hours. Time allowance is made for vacation, continuing education credits, and academic affiliation with one of the excellent dermatologic teaching programs in the New York City area. If you are interested and would like more detailed information about our practice, please contact the Office Manager, Rose Coyle at (516) 746-1227x101 or fdemento@optonline.net. Visit us at the AAD Career Fair booth 7.

CHICAGO AREA, ILLINOIS

Dermatologist/Mohs Surgeon. Dundee Dermatology invites BC/BE candidates to apply for our FT, lucrative IC position with a 2 yr partnership track. Email CV to joan@dundeedermatology.com or call (847) 851-8888. Visit us at the AAD Career Fair booth 34.

LEXINGTON, KENTUCKY

Seeking FT/PT BC/BE General Dermatologist. (859)317-1918 or leighannscaff@yahoo.com Visit us at the AAD Career Fair booth 49.

PRINCETON, NEW JERSEY

Large established Dermatology Practice seeking an exceptional Board Certified Mohs Surgeon to join a team of 7 Board Certified Dermatologists, and 3 Licensed Aestheticians in a professionally run practice that offers everything from general dermatology to our own site fully accredited histology laboratory, on-site dispensary and full complement of medical aesthetics. We also have a Board Certified Dermatopathologist on staff. Additionally, we have a fully implemented EMR, as well as a staff of over 50 employees to support our new associate. An immediate partnership track is available to the right person and we offer a state-of-the-art facility to grow your practice in a very busy, longstanding practice. Immediate opening.

Please submit your CV to trudy@thedermatologyclinic.com. Lastly, several partners will be in attendance at the AAD meeting in San Diego in March. You may contact our Practice Consultant or Practice Office Manager to arrange for a meeting at the conference at (321) 505-0302.

Supervising Physician for PA For Dermatology and Cosmetic practice start-up

Our client, a licensed Physician Assistant with 10 years of experience is starting a private practice in the Merrimack Valley area, northwest of Boston. We are looking for a Massachusetts licensed physician to act as supervisor. The SP will not be required to see patients.

Requirements and Responsibilities:

• Will review and co-sign all new patient charts and patients with Medicare who have a new problem within fourteen days. This may be done electronically.
• Must be available by phone or pager for consultation. If the SP is not available, an alternate physician will be a substitute for a limited time.
• Will agree with and co-sign the start-up practice guidelines and prescription guidelines each year.
• The SP will allow his/her information to be listed on the practice website.
• The SP will co-sign other related documents that may be related to the PA’s license renewal, DEA number and CME conference registration.
• Must be a graduate of a United States accredited medical school and have received a doctor of medicine (MD).
• Must be a member of the American Academy of Dermatology.
• 10 Years of experience in Dermatology.
• Experience working with physicians assistants is preferred.

Please forward cover letter and CV as MS Word doc attachments to: stacyorrick@orrickassoc.com.

CLINICAL DERMATOLOGIST OPPORTUNITIES

Geisinger Health System is looking for full-time or part-time Clinical Dermatologists to join our very active and growing Dermatology Department at Geisinger Medical Center (GMC) in Danville, PA and Geisinger Wyoming Valley (GWV) Medical Center in Wilkes-Barre, PA.

Geisinger’s Dermatology Department offers a friendly, collegial work environment that allows physicians to create a balance between individual practice and resident teaching while pursuing clinical opportunities in specific areas of interest. Research and publication are not required but opportunities abound.

The region boasts exceptional quality of life with a low cost of living and excellent public and private school systems. Our practice sites are surrounded by several universities, offering cultural and athletic events. Both Danville and Wilkes-Barre are within a few hours drive of New York City, Philadelphia and Washington, D.C.

Geisinger offers a very competitive salary and benefits package beginning on the first day of hire.

For more information or to apply for this position, please contact Elaine Tomashik, Professional Staff Recruiter, at 1-800-845-7112 or etomaschik@geisinger.edu.
PeaceHealth is a Washington-based not-for-profit Catholic healthcare system with seven medical centers, critical access hospitals, medical groups and laboratories in Alaska, Washington and Oregon. Founded by the Sisters of St. Joseph of Peace, PeaceHealth employs more than 14,000 caregivers and has consistently received national recognition for innovations in patient-centered care, patient safety and healthcare technology and cost efficiency.

PeaceHealth offers an employment model with a comprehensive benefit package including excellent retirement and health coverage, vacation, CME allowance, malpractice coverage, tail insurance, sign-on bonus, relocation and educational loan reimbursement.

**General Dermatologist – Eugene, OR**

We are seeking a full-time BC/BE general dermatologist with experience in medical and surgical dermatology. We offer a busy state-of-the-art facility shared with one MOHS Surgeon.

**General Dermatologist – Longview, WA/Portland, OR**

PeaceHealth, in conjunction with the Division of Dermatology at Oregon Health & Science University (OHSU), is recruiting a General Dermatologist. This unique OHSU employed with faculty appointment opportunity is based 4 days in Longview and 1 day at OHSU with no call responsibilities.

For more information, visit www.peachhealth.org or contact Carol Shea at (360) 414-7867, cshea@peacehealth.org

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**DERMATOLOGIST - Portland Metro Area & Salem, Ore**

We’re seeking a BC/BE Dermatologist to join our team of 16 Dermatologists who provide quality care to over 470,000 plan members in Oregon and Washington. Our Dermatologists have an active practice with an unusual number of complex cases and opportunities, it desired, for cosmetic procedures. We is a collegial and stimulating practice in one of the most successful managed care programs in the country. Our position includes practicing in two clinic locations: one of our Portland metropolitan clinics and our clinic located in Salem, Oregon.

We offer a competitive salary and benefit package, including a comprehensive pension program, professional liability coverage, sabbatical leave and more.

To submit your CV and learn more about this opportunity, please visit our website at: http://physiciancareers.kp.org/nw/ and click on Physician Career Opportunities. Or call (800) 813-3762 for more information. We are an equal opportunity employer and value diversity within our organization.

Visit us at the AAD Career Fair booth 26.

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**Practice dermatology the way it was meant to be... with friendly colleagues, supportive staff, and no bureaucratic headaches!**

Dermatology Associates of Wisconsin (Dermwise Dermatology Associates outside of Wisconsin) is the largest Midwest-based single specialty dermatology practice. We have more than 20 locations throughout Wisconsin, and we’re growing. Our collegial 40 member team includes 30 physicians (general dermatologists, Mohs surgeons, and dermatopathologists) and 10 mid-level providers. Our size offers you the protection of a large group, while allowing your clinic to maintain its own unique feel. Physicians have the autonomy similar to a solo practice.

Our approach to clinical practice is to work smarter, not harder. We effectively utilize medical assistants to streamline our clinics and patient flow. Our advanced Central Services further allows timely patient follow-up for prescriptions, lab results, and patient scheduling. And our in-house certified dermatology (nationally recognized program) billing specialists ensure appropriate reimbursements. All this creates an environment that eliminates the normal headaches of practicing medicine and allows you to focus on patient care! We will maximize your income with our excellent reimbursement rates, effective overhead management, along with the efficient billing and collections enjoyed through economies of scale.

Our physicians join our practice for the stability and income associated with a single specialty practice....They stay because of the professional autonomy and personal satisfaction. We pride ourselves with our commitment to a proper work-family balance that is a reality, not just a dream. Get to know us on-line at www.dermwisconsin.com and discover why Dermatology Associates of Wisconsin is making a difference in the future of dermatology!

Dermatology Associates of Wisconsin is currently seeking BC/BE dermatologists for new clinic openings throughout the Midwest as well as expansion opportunities within our practice. We are also looking for established dermatology practices to merge with/ join our practice. Contact Dan Creger, Director of Strategic Initiatives at dcreger@dermwisconsin.com or (920) 629-4840.

Visit us at the AAD Career Fair booth 23.
DALLAS, TEXAS
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WASHINGTON, DC
Visit us at the AAD Career Fair booth 5.

WISCONSIN

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Start your job search right at the 2012 Career Development Fair
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333 West Harbor Drive, San Diego, CA 92101
Visit www.aad.org/careerdevelopmentfair for more information.
At press time, Congress was still working out how to pay for extending 2011’s Medicare payment rates for the rest of 2012, having passed a two-month extension covering January and February just before adjourning for the holidays. Despite calls from most major medical associations to find a permanent solution to the ongoing Medicare payment problem caused by the Sustainable Growth Rate (SGR) formula, Congress was working on a fix for 2012 alone, setting up yet another debate on the issue for the end of this year.

The SGR formula, established by the Balanced Budget Act of 1997, sets a target for cumulative Medicare spending and requires spending in subsequent years to drop to make up for spending above the target in prior years. Thus, the price tag for eliminating the SGR continues to grow, making it harder and harder for Congress to find offsets to pay for fixing the problem. The chart below illustrates how the cost of a 10-year fix — defined simply as freezing payments at current levels — has ballooned in the last several years, and how Congressional Budget Office estimates indicate it will continue to grow over time. - Richard Nelson, MD

**Cost of 10-year SGR fix rising**
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NexTech is excited to announce that 2012 marks our 15 year anniversary. We want to thank all of our loyal clients for our continued success. As a company we are committed to no less than the highest standard of excellence. We always serve the best interests of our clients, employees, and the community.

Throughout the past 15 years, our in-house development team has worked closely with our clients to create the tools to efficiently manage their practices. As a modular system that is completely customizable, NexTech is the software that adapts to the way you practice medicine.

We are excited to release many new innovations this year including a new native iPad app, 3D EMR images, and much more. We are also excited to continue to help our clients achieve Meaningful Use and take full advantage of the incentives offered. I look forward to seeing you at one of our society events and meetings in the near future.

Kamal Majeed, Ph.D.
CEO and President