Since the introduction of cosmeceuticals in the 1980s with the discovery of glycolic acid as a topical treatment, this field has grown to a multibillion-dollar industry. In addition, it has spawned prescription treatments such as Retin-A (Valeant Dermatology) and Latisse (Allergan), as well as numerous other treatments including mineral makeup, brush-on sunscreen, tools and devices, and now, home lasers.

For this month’s column, I turned to experts from all across the cosmeceutical spectrum to gain perspective on current and future issues. Topics ranged from nanoparticles and their involvement in cosmetics to new ingredients and discoveries of receptors in the skin. Their feedback follows.

New Advances in Cosmetic Dermatology

Dr. Eugene J. Van Scott, MD and Dr. Ruey J. Yu, PhD, OMD, NeoStrata Corporation

To add to the many recent advances in cosmetic dermatology, we continue to research new beneficial ingredients and endeavor to remain at the forefront of this exciting field, while also pursuing topical therapeutic options for certain skin diseases.

Building on our early discoveries pertaining to the use of alpha-hydroxyacids (AHAs) and polyhydroxy/bionic acids for treating severe dry skin and the symptoms of aging, we continue to explore new compounds that can provide profound therapeutic benefits to all layers of skin. Deep wrinkles result from sun-induced dermal matrix degradation in combination with repetitive motion from muscular forces. These visual signs of aging can be mitigated with various dermal fillers and botulinum toxins, for patients willing to undergo injectable therapies. One of our goals in anti-aging therapy is to deliver a topical benefit to deep lines, which could be helpful to those patients who are reluctant to use injectable therapies and/or are motivated to complement the effects of the injectables and help maintain effects over time.

A new amino acid (tyrosine) derivative was uncovered as an exciting compound during our ongoing exploratory process. This compound was found to significantly build volume in the dermal matrix over a relatively short period of time when applied topically. Histological examination of Caucasian forearm skin treated with the tyrosine derivative revealed increases in viable epidermal thickness, papillary dermal thickness, as well as enhanced staining for glycosaminoglycans (GAGs) and pro-collagen. A corresponding increase in skin thickness was measured using digital calipers. In vitro studies on cell cultures demonstrated increased production of hyaluronic acid and collagen, which further helps to confirm the observed effects. In a pilot clinical study, 17 women, 35 to 65 years of age, applied...
the tyrosine derivative 2% in serum followed by 1.25% in lightly occlusive cream to target lines and wrinkles on the face twice daily for eight weeks. Clinical photography revealed noticeable decreases in deep crow’s feet, nasolabial folds, and glabellar lines. Studies with this novel tyrosine derivative indicate that it is well-tolerated topically and can be used to help restore volume to the skin’s matrix, reducing the appearance of deep lines and wrinkles.

There are many other important unmet needs in dermatology, including cosmetic improvement of hyperpigmentation, which impacts a large percentage of the global population across Fitzpatrick skin phototypes II-V. Hydroquinone can be effective, but it has been restrained from use around the world. Our objective is to find safe alternatives that are highly effective for various types of pigmentation, including melasma and solar lentigines.

To that end, we have a development program in place to explore new compounds and have identified a few potential treatment options that are being screened at present, including some additional amino acid derivatives.

Beyond anti-aging applications, we continue to explore treatment of various skin diseases that remain perplexing in dermatology. There are many outstanding treatments for psoriasis and eczema, for example. However, there continues to be an opportunity to address additional unmet needs with other novel topical therapeutic options. Ichthyosis remains a puzzle and is a passion for us; we hope to find the best possible treatment and, in the process, find compounds that influence the process of keratinization. Early-stage development of potential treatment options is in progress now.

GLOBAL INNOVATIONS IN SKIN HEALTH
Jane Iredale
Jane Iredale Mineral Cosmetics

In the immediate future, the hot news is BB Creams (short for blemish or beauty balms). The popularity of this category began in Korea and is now sweeping the world. The US is still behind Asia but is catching up. BB Creams are delighting the consumer because of their multi-tasking, an asset treasured by today’s busy woman. They give a great deal of coverage (some even have pigments that adapt to skin tones); they provide sun protection and eliminate the need for skin care. They represent a one-stop shop.

In the foreseeable future, I see makeup and skin care manufacturers alike striving to create formulas that adapt to individual skin types. Science is on the verge now of having the ability to develop moisturizers that can sense what the skin needs—more or less moisture, for example. We will see this individual adaptation becoming more important to consumers: self-tanners and users of sunscreens and makeup. It won’t be long before one shade really can fit all.

Active ingredients that produce visible results are informing all areas of the cosmeceutical world, resulting in more investigation into stem cells and nutriceuticals. The US consumer has been slow to adopt the philosophy that what you put in your body can help the health of the skin, but I think that this will change as supplements become more effective and more targeted.

THE FUTURE OF SUNSCREEN DEVELOPMENT AND REGULATIONS
Larry MacPhee, Vice President of Sales and Marketing, EltaMD

There are two possible strategic impacts that the new FDA sunscreen monograph will have on the sunscreen industry, both at retail and physician-dispensed outlets. The first impact is dictated by the required elements of the new monograph:

1. Re-testing all sunscreen products using a new set of testing procedures and scoring mechanisms.
2. Re-labeling all sunscreen products/redoing labels or boxes.
3. Re-configuring all marketing materials, including literature, website information, and any marketing information being provided by resellers (physician offices, retail stores, etc.).
4. Training all sales, customer service staff, and client staff as to the meaning of the new testing and labeling information.

The FDA estimates that the median cost to sunscreen manufacturers would be $285,000, and would take one year to accomplish. The net effect of all these elements and costs is that the price of sunscreens is likely to go up as the final implementation takes place. The FDA has initially allowed for one year (June 18, 2012) for full implementation but has since revised that date to December 18, 2012.

Perhaps the biggest challenge resulting from this first impact is that there are now many more individual terms or phrases used to describe the efficacy of sunscreens. Clinical staff will need extensive training to become familiar with these terms in order to describe to patients the performance characteristics of any one sunscreen. Training becomes key because of this.

The second impact resulting from the new monograph will be in an area not previously seen in the sun care industry (i.e., how well the criteria of this new monograph are enforced). Typically, there has been very little enforcement of sunscreen monograph claims and labeling criteria by the
FDA. It seems that, in the past, most sunscreen manufacturers have worked to get their labels and marketing claims close to those criteria spelled out in the previous final FDA monograph published in March 1999. However, even today, terms like “waterproof” or “sweat proof” are present on labels of sunscreens, terms which are not allowable.

The FDA is not technically an enforcement agency and generally avoids a blanket and detailed enforcement effort for a category of over-the-counter drugs. But there are indications that the FDA might take a more aggressive stand in the enforcement of sunscreen labeling compliance, as may be seen in the following.

1. When pressed by a collection of Congressmen, the FDA was compelled to extend the compliance date by six months, from June 18 to December 18. If they adhered to being a non-enforcement agency, a prior behavior would have been to simply let the existing compliance date stand, and disregard any concerns expressed about claims and use criteria.

2. Recent behavior by FDA inspectors suggests that they are more than willing to pursue companies violating FDA claims or packaging rules.

If the FDA does begin to enforce the criteria spelled out in the new monograph, there will be more problems for manufacturers and resellers alike. This new sunscreen monograph has significant visibility, which could mobilize the FDA in a way not generally seen in the past. Possible FDA condemnation of various sunscreens will create confusion, and force all parties to ensure that their product’s approach conforms to the letter of the law, forcing everyone to become much more of an expert on details they would rather ignore.

CONCLUSION

Part 2 of this series will include commentary from Philippe Burnham, Director of Topical Cosmeceuticals for Valeant, Diane Ranger, inventor of Bare Escentuals Mineral Makeup, and others.

Dr. Schlessinger is an advisory board/consultant, researcher, or stockholder with Allergan, Stiefel/GSK, Galderma, Obagi, Ortho Pharma (Johnson & Johnson), Medicis, and Revance. He is also President of FixMySkin, which recently introduced the 1% Hydrocortisone FixMySkin balm line.

Joel Schlessinger, MD is Founder and Course Director of Cosmetic Surgery Forum. He practices in Omaha, NE. The 2012 Cosmetic Surgery Forum will be held from Nov. 29 – Dec. 1 at the Venetian/Palazzo in Las Vegas, NV. For more information and to register, visit www.CosmeticSurgeryForum.com.

Watch Dr. Schlessinger on DermTube.com. Search for “Innovation.”