

CHAPTER 1

Cosmeceuticals and Clinical Practice

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Definition and regulatory issues

The term cosmeceutical was coined by Albert Kligman, M.D., in 1993, referring to skin care products that are a blend of cosmetics and pharmaceuticals. This term is engrained in medical literature, the lay press, and is commonly used by consumers. There is an implied medical nature as a result of “ceutical” and an expectation of medicinal-like properties. Today cosmeceutical is generally used to refer to skin care products that contain active ingredients that are beneficial to improving skin’s appearance and promoting healthy skin.

Cosmeceutical is not a legal term nor is it acknowledged by the Food and Drug Administration (FDA). The Federal Food, Drug and Cosmetic Act (FD&C Act) categorizes products as cosmetics or drugs according to their intended use. Cosmetics are defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.” Cosmetic products include moisturizers, nail polish, lipstick, eye and facial make-up, shampoo, hair color and toothpaste. This is in contrast to a drug that is defined as “an article intended for the use in diagnosis, cure, mitigation, prevention or treatment of disease,” including those intended to “affect the structure or any function of the body of man or any other animals.” While the FD&C Act does not recognize the term cosmeceutical, it acknowledges that products can be both cosmetics and drugs if they have two intended uses. For example, a dandruff shampoo that is intended to clean hair and treat dandruff makes it both a cosmetic and drug. A moisturizing sunscreen that is intended to moisturize skin and protect it from sun exposure is also considered a cosmetic and drug.

It is ironic that most cosmeceuticals in the marketplace today enjoy cosmetic status in spite of the fact they contain active ingredients designed

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to treat, mitigate or improve skin conditions. Carefully crafted marketing and advertising campaigns avoid making any type of drug claims and limited testing prevents these ingredients from being viewed as drugs. Cosmetic status is preferred by the companies who develop and market cosmeceuticals since there is a less rigorous pre-approval process required and no new drug application (NDA) necessary. This allows companies to develop and test cosmeceuticals with far less cost than drugs and moves them quickly into the marketplace at a price point that is affordable for consumers. Recent reports suggest the FDA is considering stricter regulation over cosmeceutical skin care products but the specifics are yet to be determined.

The cosmeceutical marketplace

In spite of a lackluster economy, cosmeceutical products are maintaining a strong, significant presence in the beauty marketplace. This is due by and large to the fact that Baby Boomers, who are now in their fifties and sixties, are showing a continued interest in health and beauty products. Anti-aging products remain as top performers with consistently high increases in revenue over the past several years. Cosmeceutical sales were projected to increase 7.4% in 2012, with global sales reaching US\$9.4 billion. While US cosmeceutical sales remain strong, emerging markets such as China and Brazil are expected to have significant impact on global sales. In an attempt to keep up with this demand, ingredient and end-product manufacturers are focusing their efforts on developing innovative technologies that give them unique positioning in the marketplace. Many of the latest ingredients are a blend between science and nature, making actives from botanical and marine sources among the most highly sought after in the industry.

Consumers now view cosmeceuticals as effective treatment options for a variety of skin conditions. Scientifically based marketing campaigns, celebrity and physician endorsements lend credibility to these products in the eyes of consumers. Cosmeceuticals are readily available and reasonably priced, making them an alternative to visiting a doctor and buying medications. For this reason, it is no surprise that many patients who visit our offices have tried cosmeceuticals prior to seeking cosmetic treatments. Cosmeceuticals for treating aging skin, rosacea, eczema, scars and cellulite are widely available. High end department stores promote a medical-like atmosphere going so far as to use sales persons in white coats to sell cosmeceuticals. This blurring between medicine and the mass market is unique to this category of products. And finally, there are dermatologists and plastic surgeons who market their own cosmeceutical lines. Physician lines are sold in department stores, mass retail outlets, on infomercials and home shopping channels. These lines have been widely accepted

by consumers who view physician lines as more scientifically based. The success of these lines makes physicians major players in shaping the cosmeceuticals marketplace.

Cosmeceuticals in cosmetic practice

Physicians practicing aesthetic medicine have also played a role in expanding the use of cosmeceuticals. Cosmeceuticals are now a regular part of our treatment armamentarium and are used in addition to medications and procedures to improve patient outcomes. Anti-aging cosmeceuticals are among the most frequently recommended by physicians who utilize them as an integral part of a comprehensive skin rejuvenation program. Moisturizers and serums containing ingredients like vitamin C, niacinamide, retinol, peptides, growth factors and botanicals can all be used in this regard. In addition, patients undergoing cosmetic procedures such as laser resurfacing and chemical peels may be given cosmeceuticals to “prime” the skin for procedures, encourage healing and reduce complications after.

Cosmeceuticals are also recommended for patients with acne, rosacea, eczema and other skin conditions where they are commonly used in combination with prescription medications. For example, moisturizers containing anti-inflammatory botanical ingredients may be used in conjunction with prescription medications for treating rosacea. Cosmeceuticals containing soy can be used to provide added skin lightening benefits when paired with hydroquinone. This shift in treatment paradigms has placed the use of cosmeceuticals within the purview of medical practice. Now more than ever, it is imperative that physicians understand the science behind cosmeceuticals. Patients are inundated with commercial information obtained from sometimes less than reliable sources such as consumer advertising, blogs and internet websites. They turn to their physician to provide credible advice on which products to choose and which products are worth the money. Therefore, it is our responsibility to review the scientific data and clinical studies and to steer patients away from products that are not adequately tested nor have proven benefits. This can be difficult since in the realm of cosmeceuticals, well-designed clinical trials are often lacking. Thus evaluating new products and keeping informed on the rapidly changing cosmeceutical marketplace remain an ongoing challenge for physicians.

Skin care regimens based on science

It takes time and skill to develop individualized skin care regimens for patients. Physicians must fully evaluate a patient’s skin type, assess the degree of photodamage and take into account any pre-existing skin

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conditions in order to design an appropriate regimen. It is important to consider if the patient has oily, dry or sensitive skin or if there are any pre-existing skin conditions like seborrhea, eczema, acne, and rosacea. Lifestyle considerations such as hobbies, sporting activities and occupation also play a role. A basic skin care regimen required to maintain skin health and beauty is made up of a cleanser, moisturizer and sunscreen. Toners, astringents and eye creams may also be included although these products are not considered essential. In general, regimens for cosmetic patients should include daytime products that protect the skin and nighttime products that will repair skin damage.

Cleansers are designed to remove dirt, make-up, sebum and pollutants from the skin and should be used morning and evening. Currently there are a wide variety of cleansers available, making it easy to recommend products that are appropriate for all patients. Mild cleansing products include synthetic detergent bars; these are also called syndets and lipid-free cleansers. These products have a pH that is closer to that of the skin (5.5–7) and clean the skin with little to no irritation. Syndet bars and lipid-free cleanser can be used on patients with most skin types and are especially helpful for those with dry or sensitive skin. Patients with pre-existing conditions such as eczema, rosacea and photoaging have a compromised barrier function, making gentle cleansing even more important.

Astringents and toners are used to remove any residual oils that are left on the skin after the cleansing process. Originally these products were designed to remove soap residue but today they are used primarily by patients who use cleansing creams or by those who have oily skin. Astringents and toners should be avoided in those with dry sensitive skin or in patients with a compromised barrier function. In these patients, astringents and toners may exacerbate dryness and cause burning and stinging.

Moisturizers are an essential component of a basic skin care regimen as they are necessary to hydrate the skin and to maintain barrier function. Proper moisturization can mitigate symptoms of dry skin, including itching, and improves the skin's appearance. Moisturizers are especially important for patients with conditions like rosacea and eczema where the barrier function is already compromised. Patients with oily skin and acne must also be given moisturizers since many medications used to treat acne have significant drying effects.

Photoprotection is the final essential component of the skin care regimen. Moisturizers containing sunscreens are appropriate for daily use and can be applied under make-up. Although many of these moisturizers offer good protection against ultraviolet A and ultraviolet B rays, they may not be the best choice for outdoor activities. Gel or spray-on sunscreens that are water-resistant are usually preferred by outdoor enthusiasts. Sunscreens should be selected based on skin type and personal preference.

Office dispensing

Physician-dispensed cosmeceuticals are sold in the vast majority of aesthetic practices. In 2011, dispensing lines generated US\$302.9 million in sales compared to US\$425 million sold in spas and salons, according to market research provided by Kline & Company. Healthcare and insurance companies frequently deny coverage for prescribed topical medications, making office dispensing a value added service for patients. As an extension to in-office dispensing, many physicians offer products for on-line purchase, making continuity easier for patients. Office-dispensed cosmeceuticals often contain higher concentrations of active ingredients than those available at mass market, making them more beneficial but also potentially more problematic. Nurses and estheticians can be helpful in instructing patients on proper product use and in providing information on how to treat complications should they arise.

While most patients view office dispensing as a value-added service, the dispensing physician must exercise extreme caution to keep the patient's best interest ahead of financial gain. Ethical conflicts occur when physicians are overly promotional, putting undue pressure on patients to buy products. It is important to dispense only products that have scientific validity, are clinically tested, and reasonably priced. Be familiar with retail alternatives should patients choose to purchase elsewhere. Private labeling has become increasingly popular with dispensing physicians and care should be taken to ensure that these products are not misrepresented as being physician developed or invented.

Efficacy and safety

Consumers seek products that are safe and effective. They prefer products that are fragrance-free, hypoallergenic, paraben-free, natural and green. They want products that are not animal-tested, favoring those with human clinical testing behind them. Responding to this demand, leading cosmetic companies are performing more extensive clinical testing than in years past although many studies do not meet rigorous scientific standards. Recently several major consumer companies have tested cosmeceuticals against leading prescription products. In these studies, achieving parity with prescription products bodes well with educated consumers and makes for strong marketing claims.

In spite of their long term safety profile, some consumers continue to have concerns about the safety of cosmeceuticals. Questions about the safety of nanoparticles, potential sensitizers and alleged carcinogens force many to seek natural and organic options. Natural cosmeceuticals refer to

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those with natural ingredients and are not necessarily organic. Examples of natural ingredients include aloe vera, vitamin C, soy and oatmeal. In order for a skin care product to be called organic, it must meet the new standards set by the U.S. Department of Agriculture agency in 2005. Organic skin care products must contain at least 95% organic ingredients, meaning that they were obtained from plants that were grown following organic farming guidelines. Organic crops must be grown without pesticides, hormones and chemical products, and may not plant genetically modified crops. They must also avoid any contamination during the processing of organic products. There is no scientific evidence to confirm that organic skin care products are safer or more beneficial than conventional products.

There are several excellent sources for consumers on product safety. The Cosmetic Toiletries and Fragrance Association (CTFA), now called the Personal Care Products Council, remains a trusted source on product safety. The Cosmetic Ingredient Review (CIR), a subsidiary of the Personal Care Products Council, reviews individual ingredients and determines their safety based on studies and data that are available. Information from both of these agencies is readily available on their websites and provides a valuable resource for both physicians and consumers.

Conclusion

Cosmeceuticals are now an integral part of the practice of aesthetic medicine. Physicians and their staff must be knowledgeable in order to advise patients on proper product selection and best practices. This unique category of products gives patients access to cosmetics containing beneficially active ingredients that can be used to improve the skin's appearance and treat dermatological diseases. As physicians we need to be vigilant to ensure that products recommended or sold by us are fully tested to ensure both safety and efficacy.

Further reading

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