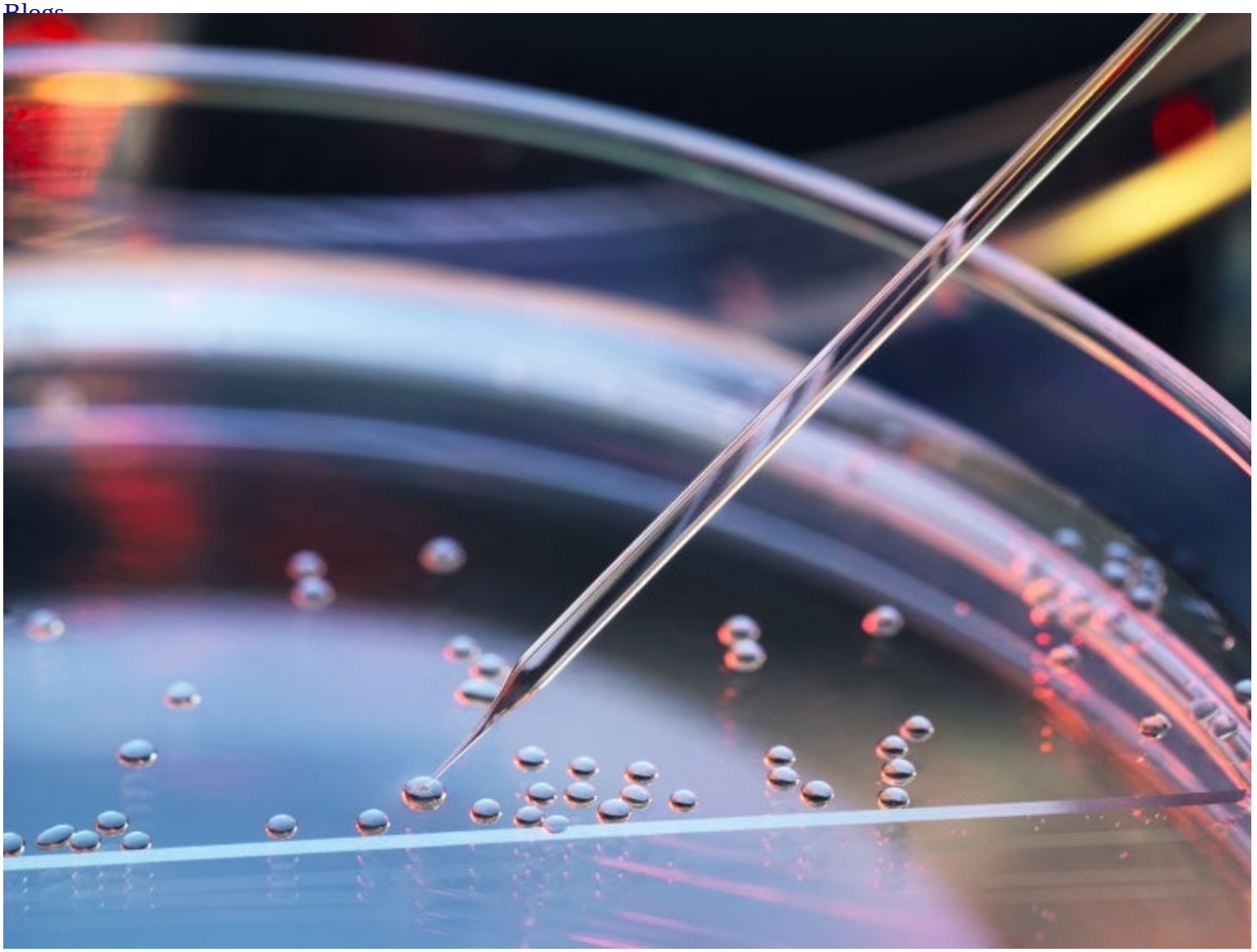

Takeaways:

- The intended uses of products are relevant to their classification as a cosmetic and/or a drug.
- Products can be regulated concurrently as both a drug and a cosmetic depending on intended uses.
- Companies should be aware of claims of intended uses of products to ensure these products are properly classified under federal law.

In recent months, the FDA has issued warning letters regarding drug claims made for products marketed as cosmetics. In light of this regulatory action, it is important for companies to appreciate the differences in how the FDA defines a "drug" product and a "cosmetic" product. The FDA regulates cosmetic products, but many products consumers consider "cosmetics" may actually be a "drug" or even "soap." In the helpfully titled

publication *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, the FDA outlined some of the important differences between these products. **What are Cosmetics and Drugs?** Federal law defines "cosmetic," in relevant part, 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." 21 U.S.C. § 321(i). This statutory definition of "cosmetic" is tied to the intended use of the product, such as cleansing or beautifying the appearance. Relatedly, federal law defines "drug," in relevant part, as "articles (other than food) intended to affect the structure or any function of the body of man or other animals" or intended for use in the "diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). The regulatory definition of "drug" connects the FDA's authority over a drug product with that product's intended use. Drugs generally face more stringent regulatory approvals compared to cosmetic products. **So What?** Given that the intended use of a product determines whether it is classified as a drug and/or a cosmetic, claims about the intended use of the product can create issues. In one seminal example, a lotion claiming to provide "a face lift without surgery" was deemed misbranded as a cosmetic and was instead deemed by the Second Circuit to be a drug and subject to government seizure. Many products are concurrently a drug and a cosmetic depending on the nature of the claimed uses. The FDA highlighted a number of these products in its guidance, such as anti-dandruff shampoo, which is intended to cleanse the hair (a cosmetic use) while also treating dandruff (a drug use). Other products identified as both a drug and cosmetic were "toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims." Such products must comply with the laws applicable to both cosmetics and drugs. In recent months, the FDA has taken enforcement action against products marketed as cosmetics with unapproved drug claims. In January 2019, the FDA issued a warning letter regarding creams and salves that, among other things, promised sun protection, reduction of inflammation, and help with arthritis, eczema, and psoriasis. In June 2019, the FDA issued a warning letter regarding products that were advertised to "control acne" and claimed to be "great for connective tissue disorders, pain, and sleep issues." A product's intended use can determine whether it is a "cosmetic" or a "drug," and, in turn, what level of regulatory scrutiny the product may face. Given the FDA's recent enforcement activity, manufacturers of cosmetics are advised to monitor the intended uses of their products as to ensure their products are appropriately classified.

Authors

Thomas (Tommy) Tobin

Counsel
TTobin@perkinscoie.com 206.359.3157

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