

**Position Statement
on
Pharmaceutical Compounding
(Approved by the Board of Directors: November 9, 2013)**

Dermatologists diagnose and treat more than 3,000 skin diseases, including skin cancer, eczema, infections, psoriasis, immunologic diseases, and many genetic disorders. Dermatologists rely heavily on compounded pharmaceutical products and especially topical compounded pharmaceutical products obtained via traditional compounding pharmacies to treat many of these skin diseases. As physicians dedicated to the safety and wellbeing of our patients, the Academy believes that a regulatory structure with appropriate safeguards is paramount to ensuring both the safety and continued access to compounded products from traditional compounders and pharmaceutical manufacturers.

The use of these types of compounded medications is an integral part of most dermatology practices and is extremely vital in providing the best patient care. A dermatology patient should have access to treatment with a compounded product in a timely manner. Over the years, dermatologists have been able to safely deliver treatments to meet individual patient needs, including patients with orphan diseases that do not have an FDA approved drug for treatment. Prescribing and/or directly administering compounded products allows us as dermatologists to tailor treatments to the unique needs of our patients, resulting in better outcomes.

Therefore, the Academy believes the following:

- Dermatologists must maintain full access to topical compounded products including in-office use without overly burdensome regulatory restrictions that could lead to unintended consequences, particularly limited or delayed access to these needed treatments resulting in increased patient morbidity and unnecessary increases in health care expenses.
- The Food and Drug Administration (FDA) should not unduly restrict access to commonly used dermatologic non-sterile compounded products prepared in a traditional compounding pharmacy.
- The Academy opposes any unnecessary requirements beyond applicable state statutes or rules that require dermatologists to provide a patient-specific prescription prior to in-office use in order to receive topical treatment with medications from a compounding pharmacy as doing so impedes access to care and interferes with the patient-physician relationship.
- As a dermatologist is ultimately responsible for the care and safety of patients in his or her practice, any non-physician provider should be directly supervised by an on-site dermatologist when prescribing or administering a compounded product. Any licensed allied health professional should also be directly supervised by an on-site dermatologist when administering a compounded product.

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- The Academy supports federal and state regulatory framework that includes consultation and input with the physicians who use compounded pharmaceutical products to ensure that a compounded product is safe, effective and meet all applicable state and federal manufacturing standards without unduly restricting patient access to compounded medications. However, as the risk presented by compounded sterile products has proven to be much greater than that of non-sterile compounded products and especially topical compounded products, the regulatory framework should explicitly recognize this through differential, risk-based regulation.
- The Academy supports a reasonable and accurate track and trace system of compounding pharmaceutical products to provide an added safeguard to enable epidemiological investigation in case of identified injury or danger to patients.

This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.