



Alliance for  
Pharmacy  
Compounding

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**Statement of the Alliance for Pharmacy Compounding's CEO Scott Brunner, CAE, on "[Compounded Topical Pain Creams: Review of Select Ingredients for Safety, Effectiveness, and Use](#)," a report released today by the National Academies of Science Engineering & Medicine:**

The recommendations contained in NASEM's pain cream study, released today, hew pretty closely to FDA's stated concerns about compounded pain creams – which stands to reason, of course, since FDA funded the study. There's not much new here. It gets some things right but misses some essential nuance, too.

The study rightly recognizes the scarcity of research on the effectiveness of compounded pain creams, and we support the study's call for additional double-blind, placebo-controlled clinical studies, which can better inform FDA's position and pharmacy compounding practice on the subject. However, the variety of combinations available to be prescribed and compounded complicates the ability to study every combination.

That's why patient-reported health outcomes also should be viewed as an integral and appropriate determinant in determining effectiveness of compounded pain gel therapies. Pain is a subjective condition, and pain gels are prepared for specific patients to address specific health needs, with prescriber, patient and compounder working together to identify the proper treatment. FDA should also weigh experiential evidence related to patient outcomes – something the NASEM study failed to consider – as it contemplates promulgating guidance on compounded topical pain creams.

One substantive shortcoming of the study is its failure to look at the relative risks of topical pain gels comparing them to other treatment options, particularly narcotic medications. While compounded pain gels are not without risks, we note that deaths related to topical pain gels are almost negligible by comparison to those from many FDA-approved oral narcotic products. That statement is substantiated in a [March 2020 report](#) from Pew Charitable Trusts showing only one death related to topical pain gel in the last 10 years. From a risk mitigation

perspective, it is concerning that the NASEM study only looked at the absolute risks of topical pain gels and not the effectiveness as compared to the FDA-approved alternatives.

APC supports the study's recommendations on standardization of labelling of compounded topical pain creams, the gist of which are already required standards for PCAB-accredited pharmacies. We're also supportive, of course, of recommendations to assure safe, *workable* state-level oversight of pharmacy compounding and of substantive training for pharmacists who compound drugs.

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*The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists, technicians, educators, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, and others. Learn more at [www.a4pc.org](http://www.a4pc.org).*