



American Academy of Dermatology

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Drug Compounding and the Dermatologist

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Forum Moderator

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Speaker Disclaimer

- The opinions and conclusions expressed in this forum are the viewpoints of the speaker(s) and do not necessarily reflect the official position of the Food and Drug Administration.

Today's Agenda

- **Introduction** – Markham Luke, MD PhD
- **What is Compounding?** – Julie Dohm, PhD, JD
- **FDA's Role in Compounding** – Julie Dohm, PhD, JD
- **Panel: Compounding and the Dermatologist** – Drs. Wilkerson, Siegfried, Alam, and Luke
- **AAD and Compounding** – Natasha Pattanshetti and Dr. Alam
- **Consensus/Future Direction** – All Faculty



Why Compounding is our main topic for this year's FDA Forum?

As dermatologists, we have a history of compounding drugs in the office or prescribing remedies that involve drugs from compounding pharmacies or having local pharmacists compound drug preparations.

- Most dermatologic compounding is for topical products being applied to the skin.
- It is important for any drug products given to patients to be of appropriate quality.



Why Compounding is our main topic for this year's FDA Forum?

- Despite compounding being an oftentimes mentioned dermatologic therapeutic tool, very little dermatologic educational activity in compounding is conducted, as evidenced in AAD syllabus, ABD Board certification questions, discussion with dermatology residents and faculty at several programs in the U.S.
- The 2012 fungal meningitis outbreak raised awareness about the need for improvement in compounding practices.
- This forum is intended to provide education and discussion on various aspects of dermatologic compounding, as well as potential recent regulatory impact.

Speaker Introduction

- Julie Dohm, J.D., Ph.D. is the FDA Senior Science Advisor for Compounding and serves as the Agency lead on compounding. She is responsible for the overall leadership of FDA's compounding initiative. She leads compounding activities of multiple offices throughout the Agency.
- Julie joined FDA as a civil litigator in the Office of Chief Counsel before moving to the Center for Drug Evaluation and Research. Dr. Dohm has bachelor's degrees in biochemistry and chemistry from the University of Chicago, a PhD in biology from Johns Hopkins University, and a law degree from the University of Pennsylvania. She was a postdoctoral fellow at Northwestern University and has clerked for federal judges in the U.S. District Court for Maryland and the U.S. Court of Appeals for the Federal Circuit.

Questions for Panel

- What are common drug products that you compound for patients in your practice?
- Why do you compound these specific products?
- What difficulties have you encountered over the years and have there been any recent changes?
- Discuss what you know about product quality, batch-to-batch variation, clean vs. sterile preparation. How might these be relevant to compounded dermatologic drugs products?
- Are there any other aspects of dermatologic compounding that you would like to discuss?